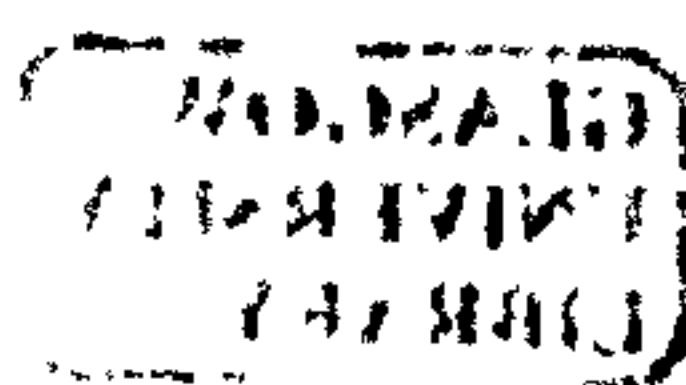


A Randomised Controlled Trial and Economic Evaluation of
Specialist Nurse Led Early Hospital Discharge Compared with
Routine Care in Gynaecology.

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PAGE

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Abstract

Background

Over the past decade the National Health Service (NHS) has undergone major modernisation and service change. There has been rapid growth in the number of new nursing role developments, despite limited evidence of their effectiveness. The evolution of such developments has been given impetus by the health service modernisation agenda and the pressures to maximise efficient utilisation of limited manpower. International evidence suggests that advanced practice nursing roles have evolved in two related but distinct directions primarily led by Nurse Practitioners (NP) and Clinical Nurse Specialist's (CNS). There is growing evidence of how these nurses contribute to improvements in services for patients in a range of care settings including acute and primary care. However, there are a limited number of empirical studies on the impact of these roles on clinical care and service delivery. There are no published randomised controlled trials (RCTs) specifically evaluating the role of the gynaecology Specialist Nurse.

The literature pertaining to gynaecology nurses focuses on the provision of alternative models of care supporting earlier hospital discharge following gynaecological surgery. Randomised trials of "Early Hospital Discharge" following elective surgery have evaluated schemes designed for patients undergoing relatively minor procedures. Several studies have focused on "Hospital at Home" care, although only one randomised trial and cost minimisation analysis of this type of care in gynaecology has been published. Schemes including "Early Hospital Discharge" following major surgery have also been piloted in a number of care settings including gynaecology. The potential role of the nurse in the provision of this type of care has been recognised. However, there have been no controlled studies of the effectiveness and cost of this type of care with support from a gynaecology nurse.

This work was designed to examine the effectiveness and cost of a new model of early hospital discharge led by a Specialist Nurse in gynaecology.

Aims

The programme of research in this thesis was a randomised controlled trial. This was designed to determine the effectiveness and cost of a new model of Specialist Nurse supported discharge and to compare this new service approach with routine care in gynaecology.

Methods

The controlled trial included three assessments, one baseline prior to surgery for benign gynaecological disease, one post operatively prior to discharge from hospital and the other at six weeks following surgery. One hundred and eleven women scheduled for major abdominal or pelvic surgery were randomly allocated to Specialist Nurse supported discharge or routine care.

The SF-36 generic health status questionnaire was used pre-operatively to measure women's own evaluation of their health state before surgery. It was also used six weeks after surgery to measure changes in health status. A further questionnaire scoring patient symptoms, milestones of recovery, information given and satisfaction, was administered after surgery prior to discharge from hospital and at six weeks post operatively. Receipt of information on return to normal activities and lifestyle issues was also assessed. Information on symptoms experienced by women in hospital, during their post-operative recovery period, including operation details, post-operative complications, length of hospital stay and satisfaction was also collected. An economic evaluation was conducted alongside the randomised trial and a cost consequence analysis was conducted based on the perspective of the NHS.

Results

The RCT showed that early hospital discharge by a Specialist Nurse in gynaecology significantly reduced the post-operative length of hospital stay, improved information for women and maintained high levels of satisfaction. There was improvement in the SF-36 health status scores at 6 weeks follow up in both groups of women. There were no differences in the number of times women

consulted with their General Practitioner (GP) and in the type of treatment received in both groups following hospital discharge. The Specialist Nurse early discharge group was associated with significantly lower total costs to the NHS, compared to routine care. This was principally due to the difference in the cost of the postoperative length of hospital stay.

Conclusions

The NHS is undergoing a major modernisation agenda and continued change is likely to encourage further development of new nursing roles. Evidence of the effect of Specialist Nurses on the development of new services and outcome of care for patients is scant in the gynaecology setting. A number of limitations were evident in the study design including the relatively small sample size and the inability to reach the estimated sample size for all of the eight SF36 health domains. There were limitations in the questionnaire designed to assess milestones of recovery and in the relatively short term follow up period of six weeks which was specifically chosen to capture any effects of early hospital discharge.

Results from the randomised study showed that women undergoing major abdominal and pelvic surgery for benign gynaecological disease were discharged home safely with the provision of support from a specialist gynaecology nurse. Findings suggest that the duration of hospital stay can be shortened by the introduction of a Specialist Nurse without introducing any adverse physical and psychological effects. This model of care was combined with giving specific information on health and lifestyle issues and maintenance of high levels of patient satisfaction. This demonstrated the effectiveness of the Specialist Nurse role in the provision of health information for women. There was no evidence that sending women home earlier increased the workload of the GP. Early hospital discharge 48 hours after major abdominal and pelvic surgery is an acceptable and cost effective alternative to routine practice in gynaecology.

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List of Abbreviations

ANA	American Nurses Association
ANP	Advanced Nurse Practitioner
ATN	Appropriately Trained Nurse
BMJ	British Medical Journal
CINAHL	Cumulative Index of Nursing and Allied Health Literature
CNS	Clinical Nurse Specialist
EHP30	Endometriosis Health Profile 30
EMBASE	Excerpta Medical Database
ENRIP	Exploring New Roles in Practice
EPOC	Effective Practice and Organisation of Care
GP	General Practitioner
HLP	Higher Level Practitioner
HMQ	Health Measurement Questionnaire
HRQOL	Health Related Quality of Life
LAVH	Laparoscopic Vaginal Hysterectomy
MOS	Medical Outcomes Study
NC	Nurse Consultant
NHP	Nottingham Health Profile
NHS	National Health Service
GUM	Genito-Urinary Medicine
NMC	Nursing and Midwifery Council
NP	Nurse Practitioner
OGNP	Obstetric and Gynaecological Nurse Practitioner
PCOSQ	Polycystic Ovary Syndrome Questionnaire
PREP	Post Registration Education and Practice
PRHO	Pre-Registration House Officer
QALY	Quality Adjusted Life Year
QUALIOST	Quality of Life Questionnaire in Osteoporosis
RCN	Royal College of Nursing
RCT	Randomised Control Trial
SF-36	Short Form 36
SHO	Senior House Officer
TAH	Total Abdominal Hysterectomy
TCRE	Transcervical Resection of Endometrium
UK	United Kingdom
UKCC	United Kingdom Central Council for Nursing and Midwifery
USA	United States of America
VH	Vaginal Hysterectomy

Chapter 1- Introduction

1.1 Background

Over the past two decades there has been considerable change in both the nature and delivery of health care. Expansion of the nursing role has been a prominent feature of health service modernisation and a range of innovative nursing roles have been introduced in a number of clinical specialities across the country.⁽¹⁾ The government White Paper “Building a Health Service- Fit for the Future” recommends that front line staff should be equipped to design service change and develop new roles and skills.⁽²⁾ This continues the government policy as set out in previous White Papers; “The new NHS – Modern and Dependable” ⁽³⁾ and “Designed to Care- Renewing the National Health Service in Scotland”, which laid out the government’s plan for the health service.⁽⁴⁾ The Scottish White Paper focused on improving the design of services and giving clinicians and those who use the services a bigger say in their management.

Health service change has been set against a backdrop of increasing public expectations, and growing cost pressures. A number of forces including; advances in technology, improved therapeutic interventions, changes in medical manpower and the introduction of government targets for waiting lists and waiting times, have all led to major service change and new roles for nurses. National workforce planning and the introduction of “Agenda for Change”,⁽⁵⁾ part of the government’s approach to pay modernisation has been a continued force for new role definition and job redesign for nurses and other staff groups.⁽⁶⁾ Implementation of both the Consultant and General Practitioner (GP) contracts ^(7,8) has influenced service provision and affected the roles of nurses. The recent publication “Modernising Medical Careers” outlines further change in junior doctors training and the effect of changes in medical careers on the shape of the service and the roles of nurses is set to continue.⁽⁹⁾

During the 1990’s, there was a proliferation of innovative specialist nursing roles in the National Health Service (NHS) but little was known about their effectiveness.⁽¹⁰⁾ Key to the introduction of many new nursing roles was the reconfiguration of specialist training for medical practitioners described in the Calman report ⁽¹¹⁾ and medical manpower pressures arising from the

implementation of the 'New Deal' for junior doctors.⁽¹²⁾ However, the rapid rate of growth in new nursing roles was in large, part due to relaxation of previous national guidance on extended nursing roles.

In 1992, the United Kingdom Central Council (UKCC) amended the "Scope of Professional Practice".⁽¹³⁾ This endorsed the principle that the limits of nursing practice be determined by the knowledge and skills required for safe, competent practice, and not by the level of specified tasks. The "Code of Professional Conduct" confirms that the individual nurse is the arbiter of role enhancement.⁽¹⁴⁾

This less restrictive approach gave nurses more freedom to extend and enhance their roles and led to widespread changes in nursing practice. These changes followed two main strands; the first was a general up-skilling of the entire nursing workforce in order to perform a range of clinical tasks that were previously the domain of the junior doctor, and the second was the introduction of a range of new specialist nursing roles. Nurses were extending their roles by taking on additional technical tasks and they were expanding practice and developing new roles, which may or may not involve the provision of technical tasks. The nursing debate focused on extension versus expansion of role, and there was confusion of these two parallel issues. This coupled with the rapid rate of growth was problematic and there was a tendency to confuse the roles of generalist and advanced practice Specialist Nurses. This situation became even more difficult because of the lack of any central policy or regulation of advanced practice nursing roles and use of titles in the UK.

In response to this the Scottish Executive and a number of Health Authorities in England commissioned evaluation and research into new roles in nursing.⁽¹⁵⁾ (1) These early exploratory studies adopted descriptive and qualitative methodologies and were the first to examine the extent of new nursing roles in the UK. The study (Exploring New Roles in Practice – ENRiP)⁽¹⁶⁾ was an extensive mapping exercise of 40 acute trusts in England, followed by case study review of 17 new nursing roles. A total of 838 'new roles' were identified of which 603 (72%) were nursing roles and only 39% of these new roles had been subject to evaluation.

This study highlights the rapid growth and lack of evaluation of new roles in the NHS in England.

In Scotland, Laurenson described 166 new roles and identified nurses working in two categories including those with additional skills which were new to existing roles and new posts which incorporate many new skills. This work identified four types of developing posts including: medical support nurses, clinical nurse specialists, advanced practitioners and practice development facilitators. These new roles were considered to be beneficial for patients, nurses and the organisation, but formal evaluation was not well established. Overall there was a general lack of understanding of the nature of new Specialist Nurse roles in Scotland.

The nursing strategy “Caring for Scotland” ⁽¹⁷⁾ recognised the potential value and contribution of nurses working within the Scottish health service. Similarly the publication for England “Making a Difference” ⁽¹⁸⁾ made reference to a range of nurse led initiatives in various settings including minor injuries management and the new nurse led NHS help line (NHS Direct). However, the literature has shown gaps in the evidence particularly in relation to the effect of nurses operating in specialist roles and providing new models of care for patients.⁽¹⁹⁾

It was also recognised that new role development was often unstructured and not part of a defined national nursing strategy.⁽²⁰⁾ A view supported by Cameron and Masterson ⁽²¹⁾ who concurred from a 20% sample of acute Trusts in England that most of the Nurse Directors vacillated between responding in an ad-hoc way to internal and external pressures or leading and supporting managed development of nursing roles. Nursing leaders were keen to influence and shape the profession and the Chief Nursing Officer for England, set out ten key roles for nurses as part of the NHS plan (2001).⁽²²⁾ These roles included; ordering diagnostic investigations (including X rays), making and receiving referrals, admitting and discharging patients for specific conditions, managing patient caseloads, running clinics, prescribing medications and treatments, resuscitation procedures

(including defibrillation), performing minor surgery, triaging patients, and taking a lead in the way local health services are organised.

Several studies have examined the roles of nurses working in a range of different specialities. There have been reported reductions in patient waiting times, improvements in service access, continuity of patient care and costs, following the introduction of new nursing roles in a range of specialties.^{(23) (24)} There is a growing body of international evidence on the effect of nurse practitioners working in the primary care setting and clinical nurse specialists providing, chronic disease management. However, there is less evidence of these nurses working in surgical specialties, particularly in relation to their effectiveness and cost of providing new models of care for patients. Nurses have been generally considered to be a cheaper alternative to doctors, although there was very little robust evidence of the cost effectiveness of nurses compared with doctors. As the health service continues to operate within a climate of escalating costs and severe financial stringency the additional costs incurred by new nursing roles becomes of particular importance. Additional financial investment for service quality improvements have been rare and new service initiatives are often based on an overall reduction of costs and cost containment strategies.⁽²⁵⁾

Evidence of the effect of Specialist Nurses providing care for women in gynaecology was scant, and little in-depth contemporary information was found on the effect of advanced practice nurses either clinical nurse specialists or nurse practitioners working in the gynaecology setting. It is important to evaluate the effect of the gynaecology Specialist Nurse because little is known about the effect and impact of these nurses on patient care. Recent opinion-based reviews have described the introduction of advanced gynaecology nurse practitioners in support of reduction in junior doctors' hours.⁽²⁶⁾⁽²⁷⁾ These reports highlighted the practice of substituting junior doctors with advanced nurse practitioners in two different gynaecology units in London and Gloucestershire. However, the roles were not described in detail and no reference was made to any evidence of the outcome of the advanced nurse practitioner roles in the gynaecology setting.

Gynaecology nurses have been shown to have a key role in the provision of structured information and adequate preparation of patients undergoing gynaecological surgery.⁽²⁸⁾ The important role of the clinical nurse specialist in providing information to help women maintain a desired health status and prevent serious illness has been recognised.^{(29) (30)} However, evidence of the effect of the gynaecology Specialist Nurse in the provision of health promotion for women is limited. To date there have been no published randomised trials on the effect of specialists nurses in the inpatient gynaecology setting in the UK. The literature pertaining to gynaecology nurses focuses on the provision of alternative models of care supporting earlier hospital discharge following gynaecological surgery. A number of descriptive studies of early hospital discharge and hospital at home schemes, have made reference to the role of the gynaecology nurse in this type of care.^{(31) (32)}

Controlled studies of “Early Hospital Discharge” following elective surgery have evaluated schemes designed for patients undergoing relatively minor procedures.⁽³³⁾⁽³⁴⁾⁽³⁵⁾ Modest reductions in post-operative length of hospital stay following major gynaecological surgery have been examined.⁽³⁶⁾ No controlled studies have examined the effects of earlier post-operative hospital discharge, following major abdominal surgical procedures in gynaecology in the UK. The main evidence available reports on “Hospital at Home” care and only one RCT and cost minimisation analysis of this type of care has included women recovering from hysterectomy.^{(37) (38)} This study did not make any reference to specialist nursing practice although the model was based on care from a hospital at home team which included the provision of nursing care. The study showed that cost effectiveness plays an important role in success or failure of new ways of working and models of care and highlighted the need to evaluate both the effectiveness and costs of providing alternative models of care. There have been few adequate economic evaluations of this type of care. Economic benefits have been found to be small because reductions in length of stay rarely represent reductions in the intensity of services provided. Reductions in length of stay may increase the intensity of care provided in the ward, although this is dependent on utilising free nursing capacity so that work can be redistributed without adversely affecting the quality of the care provided.⁽³⁹⁾

The pivotal role of nurses in the development of new and sustainable models of healthcare designed to meet the needs of patients has been recognised in Scotland.⁽⁴⁰⁾ In Glasgow, growth in the range and number of services provided by nurses operating in new roles mirrored the situation in Scotland and the wider UK. A number of new Specialist Nurse role developments continued to emerge despite lack of evidence of their effectiveness and value for money. New role developments had a tendency to be introduced in an ad hoc way. They were often supported by medical consultants and introduced because of local service pressures and medical manpower difficulties. Whilst nurses saw opportunities for change and new role development there was concern that some service developments were short-term initiatives based on non-recurring finance and not part of a national nursing strategy. The relevance of integrated workforce planning at local and national levels was recognised by the Director of Nursing of the Trust and a group of the Specialist Nurses who recognised the challenges that lay ahead, including the need to support nurses working in new and developing roles.

Structured evaluation was being encouraged in support of all new service and nursing role developments in the Western Infirmary in Glasgow. Certain specialities were introducing new ways of working for patients, supported by nurses and some evidence of evaluation was becoming apparent.⁽⁴¹⁾ The gynaecology unit in the Trust planned to implement a new Specialist Nurse role and model of “Early Hospital Discharge” for women following major gynaecological surgery. There were gaps in the evidence of both the effectiveness and cost effectiveness of Specialist Nurses in a number of settings including gynaecology and the introduction of a new model of care and Specialist Nurse in the gynaecology unit was dependant on a formal service evaluation. Previous authors have recommended that studies should assess the clinical and cost effectiveness of Specialist Nurses in each role and setting before their services are more widely adopted.⁽¹⁰⁾ Evaluation of the new model of care provided the opportunity to increase the knowledge base and examine the effects of a Specialist Nurse on patient care in the gynaecology setting.

The programme of research in this thesis was developed in response to the identified need to provide information that might help illuminate the role of

Specialist Nurse in the provision of services for patients. The research evaluated the effectiveness and cost of a new model of early hospital discharge, led by a gynaecology Specialist Nurse and compared this with routine care and standard practice in the gynaecology unit at the Western Infirmary in Glasgow. The research questions were set to address; the impact of the new model of care, and to examine differences and costs of Specialist Nurse care, compared with conventional services and routine care in gynaecology.

In order to address the research questions the study objectives were formulated. The objectives were developed to address the research questions which were posed in order to evaluate the effect of a new model of care led by the gynaecology nurse specialist. These were:

- How does the new model of early hospital discharge by a Specialist Nurse in gynaecology impact on patients?
- How does the new model of early hospital discharge by a Specialist Nurse compare with conventional service and routine care in gynaecology?
- What are the costs of the Specialist Nurse service and how do these compare with conventional service and care?

A range of research methodologies were utilised in order to answer these research questions. The primary outcome measure was the assessment of women's health status before and after major gynaecological surgery. The study hypothesised that women receiving Specialist Nurse care and earlier hospital discharge following major abdominal surgery for benign gynaecological conditions, would have significantly higher health status scores as measured by the SF-36 questionnaire compared to women receiving routine care. Justification of the methodologies adopted and details of the processes and methods used in the studies are given in the methods chapter.

1.2 Reasons for conducting the studies

My interest in this work originated from experience in a previous role working as a clinical nurse specialist in urology and gynaecology. At the outset of the thesis my role as Clinical Nurse Manager in gynaecology at West Glasgow Hospitals

University NHS Trust involved redesign of the service in support of more efficient methods of care led by nurses. I was interested in the developing roles of advanced practice nurses and was particularly keen to differentiate the advanced practice role from generalist nursing and to define and demonstrate the effects of the role on the outcome of patient care. I embarked on the work in order to help improve understanding and assess the potential contribution of these nurses to patient care.

The outcome of Specialist Nurses on patient care was scant and opportunities to explore the effect of specialist nursing practice on direct patient care were examined. Opportunities for change and service redesign were considered in the gynaecology service at the Western Infirmary, Glasgow. The doctors and nurses in the gynaecology department were keen to improve the information given to patients and support the concept of patient self-care. As a result a new service model was developed by the gynaecology nurses, in conjunction with the consultant gynaecologists and local GP's. The new model of care was specifically designed to promote the concept of patient self-care and reduce the length of hospital stay for women undergoing major gynaecological surgery for benign conditions. It was felt that patients could go home earlier following surgery with support from the Specialist Nurse and this was one way of developing the role of the Specialist Nurse and improving information and communication with patients. The model was led by a Gynaecology Specialist Nurse and comprised of early supported hospital discharge for women on the second post operative day. This reduction in hospital stay was supported by the provision of dedicated information and advice for women from a Specialist Nurse. This was considered important in order to facilitate a shorter recovery period in hospital and support convalescence at home. This formed the basis of the RCT and economic evaluation that was conducted as part of this thesis.

1.3 Structure of this thesis

This thesis reports on two related areas of research. The first part of the work was a randomised comparison of a new model of Specialist Nurse supported discharge with routine care in gynaecology at the Western Infirmary Glasgow, during 1999 - 2000. Introduction of a new model of care provided the opportunity to conduct an

RCT, the gold standard for assessing the efficacy of interventions and the best way to investigate whether cause and effect relationships exist. It was important to test the safety and acceptability of the new model of care for patients and compare this with standard care in gynaecology.

The second stage of the research was an economic evaluation and cost consequence analysis which was conducted as a sub study alongside the RCT and based on unit costs for 2003 – 2004. Value for money and cost effectiveness is important to the health service and this is now one of the deciding factors in the introduction of new models of care. It is recommended that all the relevant costs and consequences of any intervention or new model of care, are considered and compared with standard practice.⁽⁴²⁾

Chapter 1 introduces the background to the thesis and the study aims and objectives are presented in Chapter 2. The literature review is set out in Chapter 3 with the methods used in reviewing the relevant literature. The methods used in the studies are presented in two sections within Chapter 4 and the results are presented separately in chapters 5 and 6. The discussion is offered in Chapter 7 and Chapter 8 concludes the thesis with recommendations for further areas of enquiry based on the findings of this study.

Chapter 2 – Aims and Objectives

2.1 Aims

An initial literature review showed that the empirical evidence about the effect and benefits of Specialist Nurses in the provision of healthcare and in the gynaecology setting was scant. The general aims of the thesis were: ⁽¹⁾ to evaluate the effectiveness of a new model of early hospital discharge led by a gynaecology Specialist Nurse in comparison with routine care in gynaecology ⁽²⁾ to evaluate and compare the cost of both models of care.

The thesis has two chapters of results. These relate to the first and second study aims.

2.2 Objectives

The programme of research had 6 objectives, developed from the study aims.

1. To define characteristics of women receiving both the Specialist Nurse supported discharge service and routine care in gynaecology.
2. To identify if the use of a Specialist Nurse in the provision of a supported discharge service would reduce the length of hospital stay of women undergoing major abdominal and pelvic surgery, in gynaecology.
3. To determine if the model of early hospital discharge supported by a Specialist Nurse would alter health related quality of life for women undergoing major abdominal and pelvic surgery, in gynaecology.
4. To determine if the addition of a gynaecology Specialist Nurse to routine care would improve patient satisfaction levels.
5. To identify whether the use of a Specialist Nurse would improve patient compliance with lifestyle information and advice.
6. To identify whether there was any economic benefit for the Trust resulting from the Specialist Nurse supported discharge service in gynaecology

2.3 Study Hypothesis

For structural reasons in the design of the trial, neither length of hospital stay nor the expected costs were suitable measures. A limited set of hypothesis was development from the above objectives as follows;

1. There is no statistically significant difference in the health related quality of life as measured by the SF-36 in women having Specialist Nurse early supported discharge compared with those receiving routine care and standard hospital discharge in gynaecology.
2. There is no difference in satisfaction of women having Specialist Nurse early supported discharge compared with women receiving routine care and standard hospital discharge in gynaecology.
3. There is no significant difference in the cost effectiveness of Specialist Nurse responsible for providing episodes of care than routine care in gynaecology.

Chapter 3 – Literature review

3.1 Introduction

The literature review has been organised into four sections. The first part of the review examines the literature on clinical nursing role development and provides background on the scope of nursing practice, origins of Specialist Nurses and nurse practitioners in the UK and the USA. The review outlines the drivers behind new roles and examines evidence of the effectiveness and costs of specialist and advanced practice nurses working a range of different settings, including gynaecology. Section two examines the effect of surgical treatment of benign gynaecological disease and includes literature on use of health related quality of life instruments specifically the SF-36. The third section examines changes in the length of hospital stay in gynaecology and covers alternative models of care including “Early Hospital Discharge” and ‘Hospital at Home’ schemes. The last section four covers economic evaluation in health care and examines cost comparisons of different models of care.

3.2 Methods used in reviewing the literature

3.2.1 Literature search strategy

Several search strategies were employed to identify relevant literature for the thesis. Approaches used included searching the Internet, electronic databases, hand searching journal indices, examination of cross-references from relevant literature and consultation with other researchers.

3.2.2 Electronic bibliographic databases

Medline (Index Medicus and the International Nursing Index) was searched using the Ovid search engine via the British Medical Association Library. The Cumulative Index of Nursing and Allied Health Literature (CINAHL), EMBASE (Excerpta Medica) and the Cochrane Database of Systematic reviews were searched. The review includes evidence from 1966 to December 2005.

3.2.3 Search Strategies

The initial electronic search strategy was produced using key words for the different elements of the literature under examination. This generated quantities of articles under the different subject headings. This was further refined and an advanced search strategy was developed using key words. The key search terms were used to search the different databases and the search strategy was updated incrementally. The strategies used to search CINAHL, Medline, EMBASE and the Cochrane Database of Systematic reviews are shown in Appendix 1.

During the process of review relevant articles were obtained from the Library and their reference lists were examined to determine whether the search strategies were locating the relevant papers. When key papers were located, the names of the authors were used to search and crosscheck with other relevant papers. To locate 'grey literature' not included in the main databases, references from journal articles were scrutinised and the Dissertation Abstracts database was searched. Citations were scanned and papers retrieved were reviewed for the quality of their evidence using recognised critical appraisal techniques.⁽⁴³⁾

3.3 Literature – Advanced practice Specialist Nurses

3.3.1 Introduction

At the present time there is no formal recognition of advanced practice Specialist Nurse or nurse practitioner by the statutory body for registering nurses in the UK.⁽⁴⁴⁾ There been confusion caused by the plethora of new roles emerging and the range of different titles that have been used freely by nurses in the UK.^{(45) (46)} Titles used include; "Clinical Nurse Specialist", (CNS) "Nurse Practitioner" (NP) "Advanced Nurse Practitioner" (ANP) "Higher Level Practitioner" (HLP) and "Nurse Consultant" (NC).⁽⁴⁶⁾

In addition to confusion about "titles", there was also ambiguity about levels of nursing practice. There was no consensus and little consistency in descriptions of nursing practice and terms such as 'extended' and 'enhanced' were often used interchangeably.^{(47) (48) (49)} Lack of definition and ambiguous descriptions of nursing practice were evident in some uses of the phrase "advanced practice" which was frequently used to describe the adoption of a technical task rather than

as a discreet element of nursing practice.⁽⁴⁸⁾ Failure to reach consensus and regulate advanced nursing practice in the UK has left role interpretation open and often confused the descriptions of generalist, specialist and advanced nursing practice roles.⁽⁵⁰⁾⁽⁴⁰⁾

Part of the difficulty has been due to the rapid growth in the number of new Specialist Nurse roles but also because the entire nursing workforce had undergone a level of up-skilling and generalist nurses were being prepared to take on tasks that were previously the domain of the doctor.⁽⁵¹⁾ Studies described a general up-skilling of the whole nursing workforce in the UK in order to prepare nurses to take on tasks previously the domain of the doctor. The range of tasks included; venepuncture, administration of intravenous medication and peripheral intravenous cannulation, male catheterisation, cardiac defibrillation, and suturing minor wounds. This up-skilling was a significant change for the profession and some were slow to take on the tasks traditionally carried out by doctors. The changes were endorsed in the context of continuity and holistic care for patients and it was thought that some of the new skills would become intrinsic to certain nursing posts, and that nurses would be expected to carry out these roles as well as their original duties.⁽¹⁶⁾

It was recognised that whilst the acquisition of technical skill brought opportunities for job enrichment and variety, performing these tasks did not necessarily imply specialist nursing practice.⁽⁵²⁾ It was important to separate the extension and general up-skilling of nurses in certain tasks and the expansion and development of Specialist Nurses with higher levels of knowledge and decision making skills.

3.4 Nursing policy and definitions of nursing practice

Most countries have a legal definition of the title 'nurse' and some also have a legal definition of 'nursing'. These formal definitions or descriptions of nursing are used in legislation and for framing nursing policy.⁽⁵³⁾ The definition by the American Nurses Association (ANA) published in 1980 is one of the most influential definitions of nursing and has been used by several other countries and incorporated into the International Council of Nurses, 1987, definition. The

concept of the American Nurses Association definition is used in 42 of the 51 State Nursing Practice Acts.

The American Nurses Association (ANA) ⁽⁵³⁾ definition of nursing states:

“ nursing is the diagnosis and treatment of human responses to actual or potential threats to health.” ANA 1980

In contrast, there is no legal definition of nursing in the UK. The Health and Social Care Act 1990 ⁽⁵⁴⁾ defines ‘registered nursing care’ on the basis of service funding in order to distinguish from ‘social care’ and ‘personal care’. This legislative definition does not relate in any way to professional definitions or to the nurse’s scope of professional practice.

3.4.1 Scope of professional nursing practice

In the UK, legislation is not used to specify the scope of nursing practice. The responsibility for this lies with the professional nursing regulatory body, formerly the UKCC for Nursing Midwifery and Health Visiting (UKCC) now known as the Nursing and Midwifery Council (NMC). ⁽⁴⁴⁾

In 1992 the UKCC defined the scope of practice as:

“The range of responsibilities which fall to individual nurses, midwives, and health visitors related to their personal experience and skill.”

The scope of professional practice provides a regulatory framework for professional nursing practice and enables nurses to extend and enhance their role as autonomous practitioners.

3.4.2 Specialist nursing practice

In 1994, the UKCC published the Post Registration Education and Practice project ⁽⁵⁵⁾ which defined educational standards for eight specialised areas of nursing within the fields of public health and community nursing. This document draws a

distinction between practising with a specialty and being a nurse specialist and criticised use of the term nurse practitioner because all nurses practice nursing. This confused the debate on specialist nursing practice principally because the level of practice specified in the framework was also the recognised preparation to work in the community and was the initial, mandatory qualification, for practice as a Health Visitor. The practical value of the standards for specialist practice with particular regard to the emergence of new nursing roles was questionable, as many of the standards were based on traditional nursing roles and appeared to have little relevance to the range of innovative specialist roles that were emerging across the UK.

In response to the continued proliferation of new nursing roles and calls for regulation of new roles and 'titles', a pilot consultation exercise on higher-level practice was carried out within the nursing profession.⁽⁵²⁾ As a result the UKCC did not define or regulate advanced nursing practice roles or titles. The consultation concluded that specialist practice should be examined, instead of setting standards for advanced practice.⁽⁵⁶⁾ Subsequently the UKCC ⁽⁵⁷⁾ specifically defined specialist practice as a level of practice:

"Specialist practice is the exercising of higher levels of judgement discretion and decision making in clinical care. Such practice will demonstrate higher levels of clinical decision making and so enable the monitoring and improving of standards of care through – supervision of practice, clinical audit development of practice through research teaching and the support of professional colleagues and the profession of skilled professional leadership....

Specialist practice will require the exercising of higher levels of judgement discretion, and decision-making, focusing on four broad areas: clinical practice, care and programme management, clinical practice development and clinical practice leadership. This higher level of practice can be exercised in any area of health care." UKCC, (2001).

This definition identified specialist practice as a level of practice, however had limited use in terms of clarifying nursing roles. This is because it can be applied

to different concepts of practice, such as the specialist skills required to undertake a range of technical tasks and also to the advanced, higher level judgement exercised in the management of patients by expert nurses.

The new NMC reorganised in 2003, confirmed in a press statement that they intended to prescribe competencies for specialist and advanced practice and that this would include protection of the title for some of these roles. The NMC have not yet indicated which titles will be protected.

3.4.3 Advanced nursing practice

The terms “Advanced Nursing Practice” and “Advanced Practice Nurses” originated in the USA where they were used to describe nurses who have undergone curriculum based competency programmes at Masters Degree level.⁽⁵⁸⁾ The terms have also been used in the UK where there is no legislation requiring nurse practitioners to have specific forms of educational and practice preparation.⁽⁵⁹⁾ The concept of advanced nursing practice has been relatively new and examination of this has tended to focus on the roles of Specialist Nurses and NP rather than on the practice of nursing.

In the USA, Hamric⁽⁶⁰⁾ suggested that as with nurse specialists, it was possible to identify a range of core elements within an advanced practice role. In her opinion, “*advanced nursing practice is the application of an extended range of practical, theoretical and research based therapeutics to phenomena experienced by patients within a specialised clinical area of the larger discipline of nursing*”.

In the UK, McGee⁽⁶¹⁾ described advanced NP as; “*working at the frontline of the profession, trailblazing new elements of nursing and leading the way for others to follow*”. She also introduced a notion of something beyond the possession of high-level knowledge and expertise, which enables individual practitioners to function in a different way. However, the elusive nature of this difference has created difficulties in articulation of advanced practice.

The Royal College of Nursing (RCN) worked with nurses on a number of projects to help them define and describe nursing but the UKCC was sceptical about the

usefulness of definitions of nursing reporting that this would be too restrictive for the profession. The RCN argued that some specification of nursing practice was necessary for the formulations of policy, delineation of services and the development of educational programmes.⁽⁶²⁾ The RCN agreed a definition of nurse practitioner practice and appropriate educational preparation for the role.⁽⁶³⁾ The RCN and the UK nurse practitioner education programme providers adopted the competencies published by the United States National Organisation of Nurse Practitioner Facilities.

In 2002, the International Council of Nurses (ICN) arrived at a formal definition of a nurse practitioner” or an advanced practice nurse.⁽⁶⁴⁾

The ICN defined a nurse practitioner or advanced practice nurse as;

‘ a registered nurse who has acquired the expert knowledge base, complex decision making skills and clinical competencies for expanded practice, the characteristics of which are shaped by the context and/or country in which s/he is credentialed to practice. ’ A Master’s degree is recommended for entry.

International Council of Nurses 2002

To date this has been the most useful working definition of an advanced practice nurse. This definition captures the scope of advanced nursing practice and could be interpreted for use by advanced practice nurses regardless of their role title.

In the UK, there has been a growing understanding and general agreement that advanced nursing practice should consist of a clinical practice component and be underpinned by educational preparation beyond the level required for initial nurse registration.⁽⁵⁹⁾ However, in the absence of a central policy and regulatory framework for advanced nursing practice there remains a tendency to confuse the roles of generalist and advanced practice Specialist Nurses.⁽⁴⁰⁾

The terms “advanced nursing practice” and “advanced practice nurse” are used throughout the thesis to refer to all types of advanced practice nursing roles operational in the UK at the time of the study. This includes nurses who are operating beyond the level of registered nurse in a range of roles in both acute and

primary care settings including; “Clinical Nurse Specialist’s”, “Nurse Practitioners”, “Advanced Practice Nurses”, “Liaison Nurses”, “Nurse Advisors”, “Specialist Research Nurses” and “Consultant Nurses”. In this thesis, the term “advanced nursing practice” is used to denote a discrete element of nursing practice and it is not used to describe technical tasks or skills.

3.5 Origins of advanced practice nurses in the UK

The first nurse practitioner roles in the UK emerged in primary care during the early eighties.⁽⁶⁵⁾ Stilwell evaluated her role working as a nurse practitioner in a general practice in Birmingham. She described five areas of her work, which involved consultation with patients as an alternative to the General Practitioner, screening for disease by conducting physical examination, treatment of minor injuries and ailments, the provision of health education, and counselling services.

Stilwell recognised the importance of evaluating and testing the role of nurse practitioner and formulated a research project, to test the hypothesis that a nurse practitioner working in general practice could meet the needs not met by other health providers without increasing costs.⁽⁶⁵⁾ Despite this groundbreaking work and Stilwell’s strong conviction *‘that the nurse’s potential contribution in primary care remains only partly discovered’* nursing in the United Kingdom was reluctant to follow her example.

Gaze reported on the work of Barbara Burke Masters, a nurse who had been working for over four years as a nurse practitioner for the homeless, in London.⁽⁶⁶⁾ Burke Masters worked outside of the practice setting in a day centre for the homeless with the support of a General Practitioner (Dr Maurice Rosen), who gave advice, second opinions, and prescribed a range of drugs including antibiotics and tranquillisers. Burke Masters was accepted by consultants who praised her work with the homeless population, estimated to be over 5000 in East London at the time, most of whom had difficulties gaining access to a General Practitioner in primary care. Unfortunately the view was taken that the service provided for the homeless by Burke Masters was segregated from mainstream services and the homeless clinic was shut down. Burke Masters was forced to

stop her work when the British Pharmaceutical Society tried to take action against her, for dispensing restricted medicines. The work of Burke Masters breached jealously guarded professional boundaries although she was later described as a woman of immense courage and moral integrity. ⁽⁵⁰⁾

The nursing profession was cautious and resistant to new nursing roles that sought to blur the boundaries between the practice of nurses and doctors. Nursing focused attention on the development of discrete nursing roles. The first clinical nurse specialist roles emerged in specific areas of nursing practice including, stoma care and incontinence in the late 1970's. Clinical nurse specialists were seen as experts in a particular area of care or with a particular client group, with post-qualification education and a research base firmly grounded in nursing. ⁽⁶⁵⁾

3.5.1 Development of advanced practice nursing roles

A number of qualitative research studies have provided useful insights into the range of advanced practice nursing roles including clinical nurse specialists, nurse practitioners. ⁽⁶⁷⁾ The importance of discerning specific role dimensions common to most clinical nurse specialist posts including direct patient care, consultation, education and research were highlighted ⁽⁶⁷⁾ This was supported by a phenomenological investigation into the role of the clinical nurse specialists which highlighted the successful clinical nurse specialist as "*one who maintains patient care as the primary focus*". This work also recommended that elements of consultation, education and research be developed and integrated in the role. ⁽⁶⁸⁾

Hunt ⁽⁶⁹⁾ argued that health care professional's perceptions of specialists are subjective and grounded in their personal experiences and suggested that health care professionals generally confer specialist status on anyone they perceive as more experienced or specialised than themselves. Manley ^(70,71) conducted action research and recognised that expert-nursing practice can be provided by both specialist and generalist nurses although sought to differentiate by practice, which is integral to sub roles of educator researcher and consultant.

McCreadie ⁽⁷²⁾ carried out semi-structured interviews with 20 clinical nurse specialists and studied factors affecting their work with the perspective of the

researcher reflected in the substantive theory. She identified the principal role as communication with patients and described this as a unique communicator-carer role. This was thought to be key to the clinical nurse specialists' ability to carry out their role effectively and was consequently seen as the main source of job satisfaction for the clinical nurse specialists in this study. This qualitative study provided useful insight into the roles examined, but the conclusions drawn by the author about the communicator carer role are not generalisable to other groups of Specialist Nurses.

A small Delphi study examined the principle factors that influenced new roles in an attempt to identify priorities for role development.⁽⁷³⁾ The authors found that a number of different definitions which tended to reflect the focus of a particular role rather than the practice were in existence. The development of new roles was considered to be under the control of doctors and there was lack of co-operation between the professions. This small study achieved substantial consensus on nurse practitioner practice and deployment with a wide ranging expert panel. The consensus of the panel was that the culture and organisation of health care tends to hinder nurse practitioner development. These authors recommended that the Government take a more interventional role in supporting nursing developments rather than leaving this to local arrangements.

This type of qualitative research is valued particularly in areas of poor understanding and where there is little consensus on issues. However, these studies are not designed to produce robust outcome data. Most of the studies are short term evaluations, not designed to determine health outcomes. One programme of research adopted a dual methodological approach encompassing a national survey and detailed case studies.⁽⁷⁴⁾ This provided an overview of new roles and insight into the practice of this group of nurses.⁽⁷⁵⁾ However, reporting findings on new roles in this way can be problematic because due to the nature of their differences post holders are immediately recognisable.⁽⁷⁶⁾

A number of methodological difficulties have been encountered in the evaluation of new nursing roles.^{(67) (77) (78) (19)} An over riding difficulty has been the ability to attribute outcome to the effect of the nurse intervention. Several descriptive

studies into new nursing roles used survey and satisfaction measures and reported improvements in patient access and continuity of patient care. ⁽²³⁾ ⁽²⁴⁾ Patient satisfaction has been frequently used as a measurement of quality, especially in attempts to demonstrate the benefits of changes in nursing practice. ⁽⁷⁹⁾ ⁽⁸⁰⁾ Patient satisfaction is subjective and whenever it is measured, typically high levels of satisfaction have been reported. ⁽⁸¹⁾ Measuring patient satisfaction is complex because it is a multi dimensional concept and patients may be satisfied with different dimensions of their care relating to their operation and surgeon but not with the quality of the nursing care or the hospital facilities. Whilst it is recognised that patient satisfaction is not always a reliable measure of the outcome of care, minimisation of dissatisfaction and patient acceptability with the services provided is of vital importance. Patient satisfaction and engagement of patients in collaborative health care decision making can lead to positive approaches to health and the development of more patient focused services. ⁽⁸⁰⁾

Specialist Nurses were shown to be working in a range of innovative roles providing care for patients. ⁽¹⁾ ⁽⁷⁶⁾ Porter O'Grady ⁽⁸²⁾ found that Clinical Nurse Specialist's were often used for roles other than for in depth nursing practice. This was also recognised by Casteldine ⁽⁸³⁾ who described the roles of Clinical Nurse Specialist's in the UK as complex, multi faceted and changing with the needs of patients. He recognised that one of the major problems with the role of the Clinical Nurse Specialist in some settings, was shifting away from patient focused practice. The use of Clinical Nurse Specialist's in other roles, such as management, quality improvement issues, education, special projects and support activities has made it difficult to define their value within the context of patient care.

In an attempt to overcome some of the difficulties inherent in role evaluation, the NHS Executive commissioned Coopers and Lybrand to evaluate ten new nurse practitioner projects in England. This work focused on addressing key issues set down by the NHS Executive and all of the projects were evaluated within the first year of set up. The aim was to identify what makes Nurse Practitioner services different and how their services and costs compare with conventional services. Patients and professionals were surveyed to elicit information on service benefits,

patient experiences and perceptions of treatment by Nurse Practitioner's. The initial findings showed that Nurse Practitioner services were considered by patients to be more accessible, with shorter waiting times and longer consultations than conventional services. Examination of the costs was restricted because many of the impacts of the nurse practitioner were not capable of expression in monetary terms. Conventional cost benefit analysis was not carried out and it was not possible to establish if the nurse practitioner services were more or less cost effective than conventional services with any of the projects.⁽²⁴⁾

These project evaluations were carried out over a relatively short timescale and further research was recommended from each of the project sites. This included a call for national clarification of the roles of advanced nurse practitioner and clinical nurse specialists with links to salary and grade made clear, and further research on the long-term impacts of health education and patient compliance with treatment protocols. This work also highlighted the need for more robust economic evaluation and identification of the effectiveness of nurse practitioner services.

3.5.2 Similarities of advanced practice nurse roles in the UK and USA

A review of advanced nursing practice in the USA, confirmed that nursing practice had evolved in two related but distinct directions primarily led by nurse practitioner and clinical nurse specialists.⁽⁸⁴⁾ These roles emerged in America during the early sixties where they were recognised and described as advanced practice nurses despite the fact that the role origins and anticipated functions were originally quite different. Development of the clinical nurse specialist role was facilitated by the Nurse Training Act 1964,⁽⁵³⁾ and expansion of Masters nurse training programmes which made clinical specialisation the main focus.^{(58) (85)} In contrast the driver for nurse practitioner role development was a perceived shortage of physicians.

There was much controversy and division in the nursing and medical professions about the two roles with nursing openly endorsing clinical nurse specialists, whilst showing reluctance to accept nurse practitioner roles. Nurses and nurse

educationalists were enthusiastic about the role of the clinical nurse specialists; which was based on the psychosocial dimensions of care, and was seen as a legitimate nursing role. There was concern amongst the nursing profession about the validity of the nurse practitioner role, which focused on technical activities previously carried out by doctors. A commonly used description was that clinical nurse specialists followed a nursing model, and nurse practitioners followed a medical model.⁽⁸⁶⁾ In Britain nurses had a similar reaction to the introduction of these roles and have shown even more doggedness in their reluctance to accept the tasks previously carried out by doctors than their American counterparts.⁽⁸⁷⁾ Nursing in the UK was slower to accept the role of the nurse practitioner than the clinical nurse specialists.⁽⁸⁸⁾

Several American studies have shown how both clinical nurse specialists and nurse practitioner roles have developed.⁽⁸⁴⁾ ⁽⁸⁹⁾ A study of nurse practitioners and clinical nurse specialists graduates over a ten year period 1977- 1987 found similarities between the roles and raised the notion that the two roles were merging.⁽⁹⁰⁾ This study showed that nurse practitioners spent more time on direct patient care than clinical nurse specialists (73% versus 52%), and that nurse practitioners carried out physical examinations, ordered laboratory tests, made referrals, prescribed and initiated treatments, whereas clinical nurse specialists were more involved in teaching and educational roles. Despite these differences this work confirmed the overlapping function and opinions of nurse practitioner and clinical nurse specialists and the majority of graduates in this study supported merging the two roles.

A descriptive pilot study of 18 advanced practice nurse roles including posts from the United States of America, Canada and Australia showed that clinical nurse specialists had more experience in both registered nurse and advanced practice nurse roles than the nurse practitioner.⁽⁸⁹⁾ The purpose of this study was to differentiate the roles of clinical nurse specialists and acute care nurse practitioner, and determine whether the two roles could be blended. Questionnaires including self-ranking expertise in practice domains as well as valuing role related tasks were used and content validity was judged by a panel of advanced practice nurses. The clinical nurse specialists ranked their expertise

higher in all practice domains than the acute care nurse practitioners who placed more importance on tasks related to direct care including history taking assessments, physical examination and performing diagnostic procedures. The clinical nurse specialists assigned greater importance to tasks related to education, research and leadership. This small study supported the continued differentiation of the two roles.

A UK study outlined nurse practitioner competences which included; full physical examination, patient history taking, diagnostic decision making based on interpretation of clinical and laboratory results, screening patients for early signs of disease and risk factors, conducting specific invasive and non invasive diagnostic and therapeutic procedures.⁽⁹¹⁾ This also involved prescribing treatments including some medication and devising individual care plans, which include both nursing and medical management. The authors reported that these skills were also sometimes used by the Clinical Nurse Specialist, and that all of the Nurse Practitioner competencies were also potentially part of the Clinical Nurse Specialist's role.

Cukr ⁽⁹²⁾ questioned the need to merge the roles and suggested that it was unnecessary for nursing to be caught up in a 'one must predominate debate'. She indicated that both roles had been shaped by different organisational systems and educational preparations in the USA and this has led to different purposes, outcomes and research questions. This was also true in the UK where it was recognised that the development of specialist nursing roles was contingent on the prevailing organisational conditions.

3.6 Effects of reduction of junior doctors hours of work

The "New Deal" for junior doctors stipulated Junior House Officer weekly hours of duty as 72 hours minus 16 hours for rest, therefore the actual hours worked each week should not exceed 56 hours.⁽¹²⁾ Health Authorities and Trusts were asked to implement this and ensure that the contracted hours of duty for doctors in training be reduced. New nursing roles were often introduced in response to gaps in the service, as a direct result of reductions in junior doctor's hours. ^{(93) (76)}

The perspective of role substitution has been widely considered across the NHS with nurses taking tasks from doctors and support workers and health care assistants taking over some of the roles previously carried out by nurses. Enhancement of existing nursing roles and development of new nursing posts came from financial investment in support of the reduction in junior doctors' hours.⁽⁹⁴⁾ The purpose of investment was to allow substitution of medical roles and to ensure that tasks are delegated and carried out by appropriately trained staff. An example of this was when The Trent Regional Task Force for Junior Doctors allocated £500,000 to pump prime a number of innovative nursing posts designed primarily to help reduce the workload of doctors in training.⁽⁹⁵⁾ Financial penalties incurred for 'non-compliance with junior doctor hour reductions were a harsh reality and how and by whom the service is provided remains a major concern.⁽⁹⁶⁾

Several studies have compared the services provided by nurses and doctors. Although research has focused on relatively short term follow up, little attention has been paid to the costs and longer term implications of change in service provision. Hill et al ⁽⁹⁷⁾ compared the effectiveness, safety and acceptability of a nurse practitioner in a rheumatology clinic with consultant care in small randomised sample of 70 patients. Assessments were made at 4 and 48 weeks and follow up showed that patients who were managed by a rheumatology nurse practitioner suffered from less pain ($p = 0.005$), had acquired greater levels of knowledge ($p = 0.001$) and were significantly more satisfied with their care ($p = 0.001$) than those managed by a consultant rheumatologist. There was no cost analysis carried out in this study.

Campbell et al ⁽⁹⁸⁾ evaluated the effect of a nurse led secondary prevention clinics for patients with coronary heart disease. This study included a random sample of 1173 patients from 19 general practices across Scotland. The interventions at the nurse led clinics included review of blood pressure and lipid management, and follow up assessment was made at one year. This study showed significant improvement in health status in patients attending the nurse led clinic compared

with those receiving standard care by their general practitioner. There was no cost analysis undertaken with this study. Six of the eight SF-36 health domains, including physical functioning, social functioning, role physical, role emotional, pain and general health were significantly improved. There were no significant effects shown in scores of mental health or energy and vitality. Fewer patients in the intervention group required hospitalisation ($p=0.003$).

In contrast another randomised study of 1316 patients attending nurse practitioners or physicians in an ambulatory care setting in America showed significant improvements in health status in all eight SF-36 health domains in both groups.⁽⁹⁹⁾ The study found no significant difference in satisfaction with nurse practitioners or physicians at the initial follow up appointment, however at six-months follow up the physicians were rated higher ($p=0.05$). There was no cost analysis conducted with this study.

These studies comparing the care of nurse practitioners and doctors working in primary care or outpatient settings have shown positive effects. However, many studies have failed to examine the cost of care, which are of vital importance when considering the implications for change in service provision.

3.7 Meta - analysis of Nurse Practitioners

The first extensive literature review and meta- analysis of nurse practitioner in North America was conducted in the early nineties.^{(100) (101)} The review identified 900 articles of which 210 contained data on nurse practitioners or nurse-midwives. The findings showed that nurse practitioners practiced mainly in community and ambulatory care settings. Analysis of the data from the randomised trials showed that nurse practitioners ordered more investigations ($p=0.001$), scored better than physicians on the resolution of symptoms and scored higher on patient satisfaction ($p=0.001$).

More recently a systematic review by Horrocks et al ⁽¹⁰²⁾ included studies worldwide although the selection was limited to developed countries including

Europe, North America, Australasia, Israel, South Africa and Japan. This extensive search identified 119 potentially relevant papers of which 35 reported a total of 34 trials, 11 of which were randomised. Studies were included if they provided data on one or more of the following outcomes; patient satisfaction, health status, health service costs or processes of care measures including length, number of investigations, referrals, admissions, return consultations, patient adherence or measures of quality care.

Patients were more satisfied with the care provided by the primary care nurse practitioners than with doctors in 5 trials. Analysis of data from 3 trials found no significant difference in satisfaction ($p=0.4$). Consultations by nurse practitioners were longer ($p=0.001$) and they undertook significantly more investigations than doctors ($p=0.03$). Seven RCTs reported health status but the results were not included because of the heterogeneity between measures. Only five of the studies reported costs and all used different approaches for valuing resources and were inadequately powered for economic analysis. This review was limited by the many different outcome measures used and the relatively short term follow up periods of two weeks some of the studies. ^{(103) (104,105)}

3.8 Controlled trials of the effect of Specialist Nurses

A number of controlled trials have examined the effect of Specialist Nurses working in a range of different clinical specialties. There has no meta-analysis of the effects of clinical nurse specialists because of the range, variability and condition specific nature of these roles. There have been a number of different service approaches taken by Specialist Nurses working in a range of medical and surgical specialties. This has made it difficult to acquire large representative groups of staff and patients so that results can be generalisable.⁽¹⁹⁾ There are examples of nurses providing care for patients with a range of specific conditions and studies have tended to focus on the effect these nurses in the provision of chronic disease management. Limitations have been evident in studies evaluating outcomes following interventions for chronic disease management, which can take years to progress.

Examination of studies of nurses providing chronic disease management for patients has shown conflicting evidence. One randomised study by Jolly, et al ⁽¹⁰⁶⁾ assessed the effectiveness of a programme of preventative care for patients in general practice after hospital diagnosis of myocardial infarction or angina. The intervention programme assessed primary risk factors; smoking, hypertension, fitness and body mass index. Three specialist liaison nurses were responsible for the co-ordination of preventative care for patients. The specialist liaison nurses did not however provide individual clinical care to patients but provided training and support to practice nurses in preventative care strategies. The intervention in this study was shown to be ineffective in reducing risk and the reasons given for this by the authors was improvement in the standard of follow up care in the control group. However, a contributory factor was the poor design of the intervention led by the specialist liaison nurses, which was developed to mobilise rather than augment the service for patients. Although this programme was effective in promoting patient follow up in general practice it did not improve health outcome of patients. The authors recognised that the role of the specialist liaison nurse in simply supporting existing NHS care was insufficient.

In contrast Blue and her colleagues ⁽⁴¹⁾ examined a “hands on” model of Specialist Nurse care and found that trained Specialist Nurses improved the outcome of patients admitted to hospital with heart failure. In this study of a random sample of 165 patients with heart failure, 157 patients were analysed; 82 allocated to Specialist Nurse intervention and 75 to usual care. The Specialist Nurse intervention included patient assessment and a number of planned home visits supplemented by telephone contact. The study showed that patients in the Specialist Nurse intervention group had fewer readmissions for any reason ($p=0.018$), they also had fewer admissions for heart failure ($p=0.001$) and spent fewer days in hospital for heart failure ($p=0.005$). A criticism of this study is the lack of cost analysis particularly when it recognised that changes to services for patients are informed by costs as well as effectiveness. ^{(42) (107)}

This has been recognised by others and a study of the effects of community based nurses specialising in Parkinson's disease on health outcome and costs was

examined.⁽¹⁰⁸⁾ This RCT covering 438 general practices (1859 patients with Parkinson's disease), found no significant differences in mortality between those who were attending nurse specialists and those receiving routine care. Scores in the global health question were significantly better in the Specialist Nurse group ($p= 0.008$) than in routine care although there was no difference in the results of the Euroqol health related quality of life questionnaire between both groups. One of the weaknesses of this study was the small number of patients in each practice.

The cost analysis in this study included calculation of changes in health care costs for each patient in the study for two years. The authors reported that the rationale for this was the progressive nature of Parkinson's disease, which is associated with increasing health care costs to the NHS as the condition progresses. The costs included staff costs, service aids, adaptations to the home and drugs. Costs of carers and social security benefits were excluded. The mean annual costs of the Specialist Nurse group was £4050 compared with £3480 in routine care in the first year. No sensitivity analysis was reported. The costs in this study may be an underestimate of the potential costs of treating the condition because the study sample consisted of a proportion of patients with early Parkinson's disease; 50% of the patients in the study were reported as having the disease for less than 5 years. The costs of treating patients with Parkinson's disease are likely to increase as the condition progresses.

Evidence of Specialist Nurses working in surgical services was scant and few controlled studies of the effects of Specialist Nurses caring for patients with surgical conditions were found. A multi centre randomised study and economic evaluation, comparing nurses and pre registration house officers in pre operative assessment in elective surgery was examined.⁽¹⁰⁹⁾ The intervention was a preoperative assessment carried out by either an appropriately trained nurse (ATN) or a pre registration house officer (PRHO). The ATN in the study undertook training through taught Masters course modules in anatomy, physical examination and test ordering. Patient assessment involved a full general and disease specific medical history of the patient's health, a physical examination and ordering of necessary investigations guided by a protocol. There was no

difference in the pre-operative assessments in terms of under assessment of patients that might have affected peri-operative management between both groups although the PRHO's ordered significantly (50%) more unnecessary tests than the ATN.

An economic analysis was conducted alongside this RCT and a cost minimisation analysis was carried out. This estimated the expected cost per completed episode of the ATN and the PRHO and included the sum of salary costs, additional training, costs of tests correctly ordered and the costs of unnecessary tests ordered. A sensitivity analysis was used to examine the impact of changing the salaries (plus or minus 20%) of the ATN and the PRHO. This study used Monte Carlo simulation to explore uncertainty of the sample-based parameters of the model. The study model estimated the incremental cost of an ATN compared with a PRHO to be £1 and the Monte Carlo model produced a mean estimate of £0.02 pence (2%) estimate of the expected cost of substituting doctors with nurses in the role of pre-operative assessment. Despite these sophisticated modelling techniques the lower salary costs of the PRHO (£16,710 compared with the ATN at G Grade £20 145) was an important factor in this analysis, which concluded that substitution of PRHOs by ATNs was cost neutral. Economic evaluation provides decision makers with important information on which to base judgements on service change. Whilst the introduction of new nursing roles may appear to be a solution to support gaps in the service, overall there is little evidence to suggest that this is the most appropriate and cost effective approach.

3.8.1 Summary of advanced practice nurses

Evidence of the effect of advanced practice nurses on direct patient care is growing. The main body of evidence is in the provision of chronic disease management of patients with medical conditions and studies, comparing the effects of nurses and doctors caring for patients in primary care setting. Less evidence was found on the effect of nurses working in surgical specialties, where the focus of care tends to be based on recovery and convalescence of patients following surgical interventions. The range of different operational service models has made it difficult to acquire large representative groups of staff and

patients to enable generalisibility of results. Changes to services for patients are informed by costs as well as effectiveness and economic evaluation of new nursing roles and models of service is scant.

3.9 Effect of advanced practice nurses in gynaecology

To date there have been no published randomised trials on the effect of advanced practice nurses in the inpatient gynaecology setting in the UK. A small number of observational studies identify the existence of advanced nurse practitioner working in the gynaecology setting, however, these studies focus on different models of care for patients and the role of the nurse has been poorly described. Gynaecology studies have tended to focus on models of “Early Hospital Discharge” and these studies will be examined in a further section of the review.

Overall the literature reporting on condition specific gynaecology nurse practitioner and Specialist Nurse roles was sparse. One randomised study by Miles et al which examined the outcome of Specialist Nurse care at a female Genito-Urinary Clinic (GUM) was identified.⁽¹¹⁰⁾ This study compared two different models of GUM clinic, one led by Specialist Nurses who were working within protocols and the other by senior house officers (SHO). In this study 169 women were randomised to the Specialist Nurse and 178 to the senior house officer. The nurse led clinic ran alongside the SHO clinic, which was the usual model of GUM care. The Specialist Nurses and the SHO's had direct access to senior medical staff for advice. Thirty key variables were independently assessed and recorded for both groups. Patients were comparable in both groups and there were no significant differences between Specialist Nurse and SHO for 25 key variables. The Specialist Nurses performed better in 5 key variables, where significant differences were shown including; details of menstrual cycle, physical examination, medication instruction given to patients, health promotion and provision of condoms ($p=0.05$). The authors acknowledged that a methodological weakness in the study was failure to conceal staff to the random allocation at time of appointment. It was explained that the practicalities of staff managing a ‘concealed’ allocation system in the GUM clinic might have led to poor enrolment in the study. However this introduces a level of bias to the randomisation of

patients and the findings should be interpreted cautiously. The authors reported that there were no other rigorous studies to compare or judge their findings.

Two opinion-based reviews highlighted the practice of substituting junior doctors with advanced nurse practitioners in two different gynaecology units in London and Gloucestershire.^{(26) (27)} These papers did not refer to any evidence of the outcome of the advanced nurse practitioner roles in the gynaecology setting. In contrast to the small numbers of clinical nurse specialists and nurse practitioners working in the gynaecological setting in the UK, is the established practice of the Obstetric and Gynaecological Nurse Practitioner (OGNP) in the USA.⁽¹¹¹⁾ The OGNP role has been operational since the 1960's and these nurses provide comprehensive primary health care to women in the obstetric and gynaecological setting. The majority of articles in the literature refer to certified midwives and OGNPS whose roles are based on reproductive health care.

Flowers et al⁽¹¹¹⁾ examined the role of the OGNP in the USA and conducted a national study of how OGNP's obtain new knowledge upon which to base changes in their practice. This study obtained data from 1,000 OGNP's who were randomly selected by computer from the total population of 10,000 certified OGNP's. The study achieved a 94% response rate and showed 56% of the OGNP's were employed in outpatient clinics, 21% in physician's offices and 18% in public health clinics. More than half had been employed over five years and 57% indicated that their employers provided continuing education. They reported that the information on which to base practice changes was gained from continuing education meetings, discussion with physicians, drug company representatives, nurse practitioner colleagues and nursing and medical journals.

3.9.1 Health promoting behaviours of nurses in the gynaecology setting

Very little information has been published on the Specialist Nurse working in the area of women's health. Barbara Peterson Sinclair⁽²⁹⁾ examined changes in health care delivery systems and suggested that nurse practitioners were ideally placed to provide routine screening, and for teaching patients self-care and providing health promotion. Another American study by Cobb in 1998⁽³⁰⁾ outlined the

responsibilities of the clinical nurse specialist in the provision of women's health in the USA. This included prevention and promotion strategies and comprised of four role components including; clinical, education, consultant and research. The clinical role involved direct patient care including history assessment, physical examination, including breast exam and pap smear. The clinical nurse specialists can provide education during the history and physical examination and assess the patients understanding of the importance of performing breast self-examination and provide information and demonstration of the proper technique. The importance of clinical nurse specialists in helping women maintain a desired health status and prevent serious illness was recognised.^{(29) (30)}

A small number of descriptive studies reporting on the experience of gynaecology nurses in the provision of patient information in the UK were identified.^{(112) (113)} The importance of both verbal and written information was recognised by Scriven, who conducted a national survey of the written information available for women undergoing hysterectomy in the UK.⁽¹¹³⁾ A total of 93 leaflets were assessed for correctness of information and usefulness to women receiving gynaecological surgery. The authors found a need for consistency of information and a balance between general and specific information requirements. Women who had undergone gynaecological surgery and hysterectomy requested information on the physical side effects associated with this type of surgery and sought practical specific advice on activities that should be attempted or avoided following surgery, with timescales for these. This included information on return to normal household activities such as driving, housework, lifting, sexual activity, sport and work.

A publication describing the introduction of early discharge schemes for women following hysterectomy highlighted the importance of giving women specific information in a shorter timescale.^{(28) (114)} Read suggested that a nurse run pre admission clinic was the ideal time to provide women with detailed information. The author recognised the opportunity for nurses to extend their roles and provide health education and promotion for women, although the author did not provide detail of specific health promotion issues.

Walsgrove,⁽¹¹⁵⁾ suggested that gynaecology nurses in the UK have responded enthusiastically to women's health needs by giving dedicated information on HRT and early pregnancy problems. Similar reports were made by Bell ⁽¹¹⁶⁾ who described the roles of both nurse and midwife practitioner in the provision of this type of health information for women. This author reported that the quality of the service for patients improved as a result of the nurse and midwife practitioner roles but no data was provided to support this claim.

3.9.2 Summary of advanced practice nurses working in gynaecology

There is limited evidence of advanced practice nurses in the gynaecology setting. Development of Specialist Nurses in support of patient self- care and the provision of health education for women has been acknowledged in the literature. However, evidence of the provision of this type of care by nurses is scant and the need for further research in this area of nursing practice has been recognised.

3.10 Treatment of benign gynaecological conditions

This section of the review examines literature pertaining to the treatment of benign gynaecological conditions and covers the effects of gynaecological surgery on the health status of women. Gynaecological studies that make specific reference to the SF-36 health survey questionnaire were examined. This literature was examined because the new model of care led by the gynaecology Specialist Nurse, in this thesis was specifically designed to support shorter hospital stay, and promote self- care in women undergoing major inpatient gynaecological surgery for benign conditions. Assessment of health related quality of life was considered an important measure used to assess any differences in outcome and compare the effects of the different processes of care after surgery. ^{(117) (118) (119)}

Benign gynaecological disease covers a range of conditions including endometriosis, menorrhagia, polycystic ovary syndrome, chronic pelvic pain and pelvic floor dysfunction. These conditions are recognised sources of morbidity in women that can negatively affect their quality of life and often lead to gynaecological surgical treatment and hysterectomy. ⁽¹²⁰⁾

3.10.1 Gynaecological surgical procedures and treatment options

Hysterectomy is one of the most commonly performed operations in developed countries ⁽¹²¹⁾ and approximately 90% of all hysterectomies are performed for benign conditions. ⁽¹¹⁹⁾ Variation in hysterectomy rates between health authorities in the UK have been relatively low ⁽¹²²⁾ and previous studies have shown that 60% of patients who were referred to a gynaecologist with menorrhagia underwent a hysterectomy. ⁽¹²³⁾

A recent review of trends in the number of hysterectomies performed in England for menorrhagia between 1989-90 and 2002-03 has shown a 64% reduction in the number of hysterectomies performed and a 43% reduction in the total number of operations performed for menorrhagia in the UK compared with 1989-90. Ten thousand fewer hysterectomies are being performed per year. ⁽¹²⁴⁾ Being aware of this very substantial fall in hysterectomies is important because of the implications for service provision. The reduction in hysterectomies to may be partly attributed to advances in treatment options for benign gynaecological conditions and changes in approaches to management. During the nineties two significant changes occurred; Endometrial ablation treatment was introduced and shown to be a viable surgical alternative to hysterectomy. ⁽¹²⁵⁾ The Levonorgesterel intrauterine device (Mirena Schering) has also been effective in reducing menstrual bleeding and shown to reduce the number of women proceeding to hysterectomy. ⁽¹²⁶⁾

Reported side effects after hysterectomy including treatment complications and bladder problems, has meant the impact of the procedure on health related quality of life is particularly important. ⁽¹¹⁹⁾ The next section examines the literature on the effect of gynaecological conditions and treatment on health related quality of life of women.

3.11 Effect of gynaecological conditions on health status

Over the past few decades, there has been increasing interest in the development and use of patient assessed health outcomes and the importance of subjective health measurement in the assessment of health interventions has been

recognised.^{(127)(128) (129)} The adverse impact of gynaecological conditions on women's quality of life has been well documented in a number of population based studies.

The first systematic review of the use of Health Related Quality of Life (HRQL) measurements in the treatment of benign gynaecological conditions, including endometriosis, menorrhagia, polycystic ovary and chronic pelvic pain was published in 2002 by Jones et al.⁽¹²⁰⁾ The basis of this systematic review was to identify the impact of symptoms and treatment of these conditions on health status. Papers were retrieved by systematically searching 6 electronic databases - Medline, EMBASE, PsychINFO, the Royal College of Nursing Index and Cumulative Index to Nursing and Allied Health Literature. A total of 1715 publications were identified and many of the articles appeared in more than one database and were not relevant to the study because they referred to gynaecological malignancies (94%). A total of 103 papers were relevant - 54 were discarded because they were unobtainable and 4 because they made reference to quality of life in the abstract only. The search identified 46 relevant studies, 34 used standardised instruments of which 23 used generic tools.

Rowe et al⁽¹³⁰⁾ examined the association between benign gynaecological conditions and quality of life in women before hysterectomy and placed women in four symptom based groups of; pain, bleeding, pelvic discomfort and no symptoms. Health related quality of life was measured using six scales, that were developed from items taken from the Maryland women' health study and the SF-36 generic instrument. The health related quality of life of women with endometriosis and pelvic pain was significantly lower than women with the other symptoms. Before undergoing hysterectomy these women measured worse on sexual function role, mood, severity of symptoms and perceptions of general health.⁽¹³⁰⁾

Slightly different results have been reported on women's health related quality of life in gynaecological conditions where pain was not a primary symptom. An example of this is shown in the condition menorrhagia, which has been found to

have a variable effect on health related quality of life in women. ⁽¹³¹⁾ Ruta et al found that women with menorrhagia had major effects in social functioning and reported that this condition affected (in order of importance) family life, physical health, practical difficulties associated with heavy bleeding and social life. This was in contrast to findings of Coulter et al who reported the most frequently cited impact was on mood and irritability. ⁽¹³²⁾ This study of 483 women from 73 General Practices in Oxford examined quality of life and patient satisfaction following medical and surgical treatment for menorrhagia. Baseline data was obtained by a postal survey at the start of the study and again at eighteen months. Women reported improvement in their quality of life after treatment for menorrhagia, with much greater benefit reported by women having surgical treatment than those who had not. Results should be taken in context. This was an observational study of normal clinical practice and not a controlled trial.

A meta-analysis of studies in the systematic review of health related quality of life measurement in women with chronic benign gynaecological conditions was not possible, although the authors concluded that women with chronic pelvic pain and conditions associated with pelvic pain (such as endometriosis) report worse health related quality of life. In relation to treatment outcomes, medical treatments can cause significant improvements in health related quality of life although these appear only to be short-term improvements. Surgical procedures both hysteroscopic and hysterectomy have been shown to be more beneficial than medical treatments in improving women's health status in the longer term. ⁽¹³³⁾
⁽¹³⁴⁾

3.11.1 Gynaecology disease specific measures of health status

The limited use of generic tools in the measurement of health related quality of life in chronic conditions such as chronic pelvic pain and endometriosis was recognised. This is particularly so with the SF-36 questionnaire because of the small number of questions in the pain scale and the specific time frame on the questions (including past 4 weeks and past year) which do not allow the chronic complex nature of pelvic pain to be fully expressed. Disease specific questionnaire developed with items generated by patients with the condition demonstrate face validity and are considered more appropriate for use in certain

conditions such as endometriosis. Although seven studies in the review reported on disease specific questionnaires however only two of these studies reported on questionnaire items developed from patient interviews. ^{(135) (136)} The review was limited in that only 8 randomised studies had used standardised instruments to measure the health related quality of life after treatment and only 3 studies reported on longer term follow up. The relevant randomised studies utilising the SF- 36 survey are examined separately.

3.11.2 SF-36 health survey questionnaire in gynaecological studies

The benefits of health related quality of life measurement has been shown in evaluative research, particularly in controlled studies designed to measure health status before and after gynaecological surgery. The SF-36 has been recommended for use in the evaluation of new medical interventions and clinical trials in the gynaecology setting.⁽¹²⁹⁾ The generic SF-36 health survey questionnaire measures three aspects of health; functional status, wellbeing and overall evaluation of health using eight separate scales. ⁽¹³⁷⁾ The instrument has been validated for use in a range of patient populations ^{(138) (139) (127) (140)} and in the gynaecology setting where it has been shown to be sensitive in the measurement of health related quality of life in women following hysterectomy and other gynaecological surgical interventions. ⁽¹¹⁸⁾⁽¹⁴¹⁾ Studies utilising the SF-36 as a health related quality of life measure, whilst comparing the effects of medical and surgical treatment of benign gynaecological conditions were examined further.

One observational study of 309 women with heavy menstrual bleeding by Jenkinson, et al ⁽¹⁴²⁾ compared the sensitivity to change of the SF-36 multi dimensional health status measure with a single global health status measure. Women either received drug treatment alone or both drug treatment and surgery. Those receiving drug treatment alone did not report any substantial effect on any aspect of their health status, whereas women undergoing surgery had moderate to substantial effects on six of the eight domains in the SF-36 questionnaire. This study confirmed significant change in SF-36 scores following surgical intervention with improvements in social functioning, energy, pain and mental health. However, the physical functioning score was not improved after surgery

and the authors concluded that it was unlikely that the surgical procedure would dramatically improve physical function.

Cooper et al ⁽¹⁴³⁾ compared medical treatment with the surgical procedure TCRE and showed that this type of surgery leads to greater improvement in health related quality of life than medical treatment alone. In this study 197 women were randomly allocated with 94 to medical treatment and 94 to TCRE. The main outcome measures included; treatment satisfaction and acceptability, relief of symptoms and improvement of health related quality of life assessed by the SF-36. Results at four months identified that women undergoing TCRE were more likely to be totally or generally satisfied (76% versus 27% $p = 0.001$) and (93% versus 31% $p = 0.001$) found the treatment acceptable. Pain and bleeding, was significantly reduced by medical management, although this was a modest reduction in comparison to TCRE; ($p = 0.001$). Change in the SF-36 scores at four months was significantly higher in the TCRE group.

A two-year follow up study supported findings from the first study and showed significant improvements from baseline SF-36 scores. The follow up scores showed improvement in five of the eight dimensions of the SF-36 questionnaire in women who received medical treatment compared with improvement in seven dimensions in the TCRE group of the trial. There was no significant improvement found in the general health dimension of the SF-36 in both groups. At the two year follow up a number of women in the medical group had gone on to have a TCRE procedure. Further follow up at 5 years showed only 7 women (10%) of those randomised to medical care still used medical treatment while 72 (77%) had undergone surgical treatment of endometrium and 18 (19%) had had a hysterectomy. ⁽¹¹⁸⁾⁽¹¹⁷⁾

The pragmatic study design that was adopted developed potentially predictable methodological difficulties with the long-term follow up. The difficulty in maintaining sample size for follow up comparisons in this study was because the sample was made up of women seeking specialist treatment for heavy menstrual loss for the first time and women who were willing to accept either treatment; medical management or TCRE. For ethical reasons women in the study were not

denied any further treatment whilst they were participating in the study. The authors also acknowledged a view that the medical management tested in the study could be considered sub optimal.^{(118) (117)} However, this work provided a valuable insight into the effect on quality of life of women following both medical and surgical treatment for menorrhagia.

Introduction of surgical interventions TCRE and MEA has given women the option of less invasive surgical treatment for menorrhagia than hysterectomy.⁽¹¹⁸⁾ A randomised comparison of hysteroscopic and endometrial ablative techniques used the SF-36 health related quality of life questionnaire at recruitment and 12 months after operation to measure the impact of TCRE on quality of life compared with Microwave Endometrial Ablation (MEA). In this study 263 women were randomly allocated; 129 to Microwave Endometrial Ablation (MEA) and 134 to Transcervical Resection of the Endometrium (TCRE). The results showed improvement in all of the eight SF-36 dimensions with six significantly ($p = 0.001$) in the MEA group and seven of the eight dimensions improved significantly ($p=.05$ to $.001$) after TCRE . Both techniques achieved high rates of satisfaction and acceptability and improved quality of life after one year.

3.11.3 Summary of health related quality of life measures

The benefits of health related quality of life measurement in evaluative research are well recognised particularly in RCTs. Several studies have been designed to measure health status before and after gynaecological surgical treatment. Health related quality of life measures have reliably demonstrated the short-term impact of gynaecological procedures including hysterectomy on health related quality of life in women and may be useful to test changes in treatment regimes and different types of care provided in alternative conditions or settings.

3.12 Length of hospital stay in gynaecology

The new model of care under study in the thesis encouraged shorter hospital stay following major gynaecological surgery. One of the aims of the new model of care was to reduce the length of hospital stay without adversely affecting the quality of care. This section of the literature examines changes in the length of

hospital stay and periods of recovery following gynaecological surgery. A number of early observational studies examined the effects of shorter hospital stay following vaginal hysterectomy.^{(144)(145) (146)} The primary motivation in two American studies was the desire to economise on the cost of medical care. Stovall et al⁽¹⁴⁴⁾, tested the feasibility and safety of sending women home on the same day of the operation, however, the sample of 35 women was very small and patients were highly selected. Reiner⁽¹⁴⁵⁾ discharged 41 women who attended his private practice 24 hours after vaginal hysterectomy. However, this small study was of poor methodological design and showed no evidence of statistical analysis to support the claim that none of the patients required readmission to hospitalisation because of undue pain, bleeding, infection or other commonly associated morbid complications.

Similarly a small observational study of women undergoing early hospital discharge following vaginal hysterectomy in the UK was conducted to test the safety of earlier hospital discharge.⁽¹⁴⁷⁾ Two research staff nurses with experience in gynaecology supervised planned early discharge of 30 women 72 hours following vaginal hysterectomy. The main outcomes reported by the authors were minor post-operative complications and acceptability. The study design was disappointingly inadequate, the sample was small and women were highly selected and not representative. There was no power calculation given and the study was unable to detect a difference in complication rates following early discharge.

Clinch⁽⁸⁶⁾ reviewed the length of postoperative stay of 378 women undergoing vaginal hysterectomy between 1986 and 1992 in two gynaecological units in Dublin. He demonstrated an overall reduction in the total bed days and mean hospital stay from 555 total bed days and a mean stay of 7.0 days in 1987, to 153 total bed days and a mean stay of 3.4 in 1992 following vaginal hysterectomy.

These pilot studies show attempts to reduce the length of hospital stay in gynaecology following vaginal procedures, which are less invasive and have shorter recovery periods than major abdominal hysterectomy. These early studies

appear to have been intended to test safety and not designed to provide unequivocal results on patient outcome.

3.12.1 Laparoscopic Vaginal Hysterectomy

More recently, the introduction of Laparoscopic Vaginal Hysterectomy (LAVH) has influenced reductions in the length of post-operative hospital stay in gynaecology in the UK. The post-operative length of stay following this procedure has reduced whilst the length of stay following abdominal surgery has remained fairly static. Reductions in post-operative length of stay following laparoscopic procedures have been implemented in attempts to offset the increased cost of disposable items and longer operative times associated with the procedure.⁽¹⁴⁸⁾

In 2004, Garry et al⁽¹⁴⁹⁾ conducted the largest controlled trial, comparing both Vaginal Hysterectomy (VH) and Total Abdominal Hysterectomy (TAH) with Laparoscopic Vaginal Hysterectomy (LAVH). This work included two parallel multi-centre RCTs in 28 UK and 2 South African centres including 1346 women who were followed up for one year. The primary endpoint of both studies was major complication rate and the secondary endpoints were minor complication rates and questionnaire assessment of sexual activity, body image and health status using the Short Form 12 (SF-12) quality of life questionnaire.

In the vaginal arm of this study there was no difference found in major complications between LAVH and Vaginal Hysterectomy, although this part of the evaluation was underpowered. The length of stay for both groups was 3 days and there was no difference in pain and quality of life at any point in either group. LAVH took significantly longer to perform than the vaginal procedure (72 v 39 minutes).

Results from the abdominal trial showed that LAVH is associated with a higher rate of major complications than Abdominal Hysterectomy ($p=0.02$) and is a longer operative procedure (84 vs 50 minutes). LAVH resulted in shorter lengths of hospital stay; 3.95 days compared with 5.11 days for the abdominal procedure. Improvement in the physical and mental components of the SF-12 was shown in

both the vaginal and abdominal trial. There was a highly significant difference in the physical component summary score of the SF-12 in the group undergoing LAVH compared with those undergoing abdominal hysterectomy.

Sculpher et al ⁽¹⁵⁰⁾ conducted a cost effectiveness analysis of LAVH compared with standard hysterectomy within the RCT by Garry et al.⁽¹⁴⁹⁾ Costs were analysed over one year from the NHS perspective. The comparison found that LAVH cost an average of £186 more than the abdominal route. A sensitivity analysis assessed how differential costs would change if all laparoscopic procedures had been undertaken with reusable equipment. The mean difference between Vaginal Hysterectomy and LAVH was reduced to £268 and the mean difference between Abdominal Hysterectomy and LAVH was £72.00. LAVH is a more expensive procedure because of higher disposable costs and longer operative lengths than both Vaginal and Abdominal Hysterectomy, with vaginal hysterectomy being the least costly of the three procedures.

These studies have shown that laparoscopic approaches to hysterectomy offer improved outcomes and gains in cost effectiveness, through reduced convalescence and shorter lengths of hospital stay. These studies have shown, that patients undergoing minimally invasive laparoscopic surgery require less hospitalisation and reduced convalescence than women undergoing abdominal hysterectomy.⁽¹⁴⁹⁾ The length of hospital stay in gynaecology is procedure specific with shorter stays reported for vaginal and laparoscopic surgery than abdominal procedures.

3.12.2 Abdominal Hysterectomy

In most countries, including the UK and USA the abdominal approach to hysterectomy predominates over the vaginal route particularly when dealing with more serious pelvic disease and carrying out Oophorectomy at the same time.⁽¹¹⁹⁾ Therefore change and reduction in length of hospital stay following the abdominal procedure is important in order to reduce unnecessary hospitalisation and associated costs of care.

Recent randomised controlled trials by Garry et al and Lumsden et al confirm that the post operative length of hospital stay following abdominal hysterectomy remains at 5-6 days.^{(149) (148)} To date there have been no randomised trials of the effects of early hospital discharge on post- operative day 2 or 3 following abdominal hysterectomy in the UK. Formal evaluation of changes in hospital length of stay, is scant in the gynaecology setting. An earlier prospective cohort study of 363 women undergoing abdominal hysterectomy for benign conditions examined the effects of a modest reduction in post operative length of stay from six days or more to 5 days following the abdominal procedure. This study was specifically designed to identify whether shorter length of hospital stay was associated with poorer health outcome, as measured by the Nottingham Health Profile (NHP) formal and lay care and costs.⁽³⁶⁾ One group of 112 women were allocated in a non- randomised manner to a short post-operative stay of five days or less and 251 women received standard length of stay of six days or more. Of the 363 women in the study 112 stayed in hospital for 5 post- operative days, 160 stayed for 6 days, 46 stayed for 7 days and 45 stayed 8 days or more. The shorter post-operative length stay in the intervention group was 5 days and the standard post-operative stay remained at 6 days or more. This study involved a modest reduction in length of post-operative stay and women in the shorter stay group spent 1.79 days less in hospital after hysterectomy than women receiving standard stay.

Women in the shorter stay group, were found to be less likely to have a wound infection in the first 10 days ($p=0.03$) suffer from constipation ($p=0.001$) and complain of urinary symptoms at six weeks ($p=0.004$) and three months ($p=0.008$). Both groups showed similar outcomes as measured by the NHP quality of life questionnaire except for the physical component of the NHP which deteriorated in women in the longer stay group. There was no difference in general practitioner consultations and lay care in both groups after discharge.

Costs were calculated at for the last 24 hours before hospital discharge in both groups and a comparison of the mean cost difference was £251 more in the longer stay group. The rationale given for calculating costs only in the last 24 hours was

because this period was regarded as the low dependency end of hospital stay. However, a more detailed cost analysis of the total costs for both groups for the duration of their hospital stay would have given a more accurate estimation of the costs and cost difference between the groups. There was no sensitivity analysis reported with this study.⁽³⁶⁾ This study of earlier hospital discharge on post-operative day 5 showed no detrimental effect on the health of the women or need for post discharge care. The modest reduction in length of hospital stay following abdominal hysterectomy gave support to the notion that women could be safely discharged earlier following abdominal hysterectomy.

A small prospective descriptive study of 32 women with planned lengths of stay of 2 days following abdominal hysterectomy and 1 day after laparoscopic assisted vaginal hysterectomy (LAVH) in a fast track setting demonstrated that it is possible to reduce the length of stay following abdominal hysterectomy.⁽¹⁵¹⁾ This study challenged the suggested advantages of shortened hospitalisation after laparoscopic assisted vaginal hysterectomy LAVH compared to abdominal hysterectomy and questioned the true need for convalescence after both procedures. Caution should be taken however when interpreting the results as the numbers in the study were small. The total sample of thirty-two women were allocated by their consultant in a non- randomised manner until sixteen patients were reached in each group. Results were also possibly influenced by the pre-defined reduction in length of stay, and the selection process and pre conceptions of patients. Five patients in each group did not feel ready for discharge as scheduled and nine women stayed longer because of fatigue, abdominal pain, insecurity and dizziness.

There are a number of criticisms of this study and the difference in hospital stay, may merely reflect the length of stay that was pre defined at the start of the study. A larger sample and more rigorous selection of patients and use of blinding techniques would have minimised potential treatment bias. However, this small study highlighted the importance of preparing patients adequately for their surgery and post-operative recovery and suggested this was key to the success of early discharge schemes. No controlled studies have examined the effects of reducing

the post – operative length to 2 days or more in women following hysterectomy in the UK.

3.12.3 Summary of length of hospital stay in gynaecology

Lengths of hospital stay in gynaecology are condition specific with shorter stays reported following vaginal and laparoscopic procedures than for abdominal surgery. Recent studies confirm that the length of hospital stay following abdominal surgery in the UK has remained fairly static at between 5 and 6 days. Results from pilot studies have shown that further reductions in hospital stay following abdominal hysterectomy are possible. There have been no controlled studies on the effects of shorter post- operative length of hospital stay of 2 days in women undergoing abdominal hysterectomy in the UK.

3.13 Alternatives to hospital care

Several studies have examined different methods of organising and delivering care for patients. Principally, these have focused on models aimed at reducing the length of time spent in acute hospital care. This section reviews the evidence of alternatives to hospital care including, “Early Hospital Discharge” and “Hospital at Home” schemes. Particular reference is made to gynaecological studies where the role of the nurse in support of earlier hospital discharge is identified and the costs of care are examined.

The terms “Early Hospital Discharge” and “Hospital at Home” are sometimes used interchangeably. Evaluation can be problematic because whilst these schemes have a similar purpose in reducing inpatient hospital care, the care provided can take different forms. These can represent different levels of care provision depending on the needs of the groups and population they serve. Coast highlighted the need for evaluation of alternatives to hospital admission and recognised that patients should have a much greater voice in deciding how care is delivered. ⁽¹⁵²⁾

3.13.1 “Early Hospital Discharge”

Models of “Early Hospital Discharge” have tended to focus on specific specialty based conditions rather than a range of conditions from different specialties. This contrasts with “Hospital at Home” a model of care often developed to provide care for patients with a range of different conditions. The first UK controlled study reporting on outcomes and cost effectiveness of “Early Hospital Discharge” in the surgical setting was a randomised study of patients, following surgery for hernia and varicose veins.⁽¹⁵³⁾ Patients were randomised into two lengths of post-operative stay 48 hours or six to seven days. One hundred and seventeen patients were randomised to short stay and 107 to standard stay. This study showed a significant increase in all complications for patients recovering from varicose vein surgery.

In the same year, another randomised trial of 360 patients undergoing surgery for varicose veins and hernia managed 121 patients in an acute ward for 48 hours, 122 patients were cared for in a convalescence hospital for 48 hours and 117 were discharged directly home into the care of a district nursing sister and a general practitioner.⁽³⁴⁾ This study showed no major complications in any of the three groups. Minor complications were recorded in one third of the patients in all groups and no significant difference was detected in the medical outcome between the three groups after operation. Day care was the most economical of the three options and this group obtained the highest proportion of favourable responses from patients.

A more recent surgical study by Bundred et al ⁽³⁵⁾ examined the effects of early discharge after surgery for breast cancer. This study adopted a similar methodology to previous studies of early hospital discharge and randomised women to short stay of 48 hours or standard stay of 6 days.^{(153) (34)} At the time of this study the average hospital stay after surgery for breast cancer was seven days in the UK. Findings showed earlier hospital discharge two days after surgery did not affect the rate of complications and psychological illness. Three months after surgery women, in the earlier discharge group reported greater shoulder movement ($p=0.042$) and less wound pain than women receiving standard hospital

discharge ($p= 0.016$). This study concluded that short hospital stay with support from specialist breast care nurses at home is acceptable to patients. A common theme in all of these studies was the contribution and role of the nurse in the follow up care of patients after early discharge. Adler et al, ⁽¹⁵³⁾ reported that all but one of the short stay patients were visited by district nurses.

Whilst these studies report earlier hospital discharge, the concept of the models of care can differ from “Hospital at Home” care which discharges patients early from acute hospital care and transfer them into a hospital at home scheme for a pre defined period of time. Early discharge schemes often provide care and rehabilitation for a specific condition, whereas “Hospital at Home” schemes, on the other hand tend to provide care for a range of patients with different conditions.

3.14 Models of “Early Hospital Discharge” in gynaecology

Several small observational studies of early hospital discharge following gynaecological surgery were found and are reported in the thesis. These studies provide useful insight into the models of early discharge and different methods of organisation of care in the gynaecology setting. These studies are examined and reported in detail in this section. ^{(31) (32) (36) (151) (154)}

3.14.1 Early Hospital Discharge by Community Liaison Nurses

A small descriptive study of early supported discharge by community liaison nurses included a total sample of 72 patients who were pre selected and allocated early discharge on day three or four post operatively, with 22 patients receiving standard discharge on day seven post operatively.⁽³¹⁾ Women in the early discharge group were visited at home by the liaison nurse on days, four, five, seven, eight and fourteen and post-operative assessments were made of both groups on day's 7, 10 and 14. All the women in the study were followed up for fourteen days. A selective patient criteria was used for the early discharge group and this excluded all women over 60 years and those with other medical or surgical conditions. The overall study methodology and findings were not well defined or described. There was no detail of the role of the gynaecology liaison

nurse and the requirement for the number of home visits that these nurses made to women in the early discharge group. The potential for transferring the burden of care on to the community was recognised but the authors concluded that no extra workload was placed on general practitioners and district nurses despite limited evidence to substantiate this. The authors did not make any reference to the cost of both types of care.⁽³¹⁾

3.14.2 Early Discharge with General Practitioner follow up

An observational study of early hospital discharge with non-specified general practitioner follow up care was carried out in the gynaecology setting.⁽¹⁵⁴⁾ The sample included 100 hundred consecutive women who were allocated in a non-randomised manner to two groups of 50 women. One group of women were discharged early from hospital on post-operative day three and the other group received standard discharge up to seven days post operatively. The study methodology consisted of a questionnaire to patients and their general practitioners at 3 months follow up. Results showed that both groups were age matched and the median post-operative hospital stay in the early discharge group was 3 days compared with 5 days in the standard discharge group.⁽¹⁵⁴⁾

A 97% response rate was obtained from the GP questionnaire. There was no difference in the rate of complications reported by the attending general practitioners who diagnosed 39 post-operative complications in the early discharge groups and 32 in standard discharge. A total of 36 home consultations were required in the early discharge group compared with 13 in standard discharge ($p=0.05$). There was no difference in the number of surgery consultations with the general practitioner (53 v 57) in both groups of women.⁽¹⁵⁴⁾

The response from the patient questionnaire was also high, at 87% and the majority of patients in both groups reported that their hospital post-operative convalescence was of the correct duration and return to daily activities was similar. The authors reported that whilst the majority of patients were happy with their duration of hospital convalescence in both groups, there was a tendency toward greater dissatisfaction in the early discharge group. There were

deficiencies with the design of this study including lack of randomisation and concealment. Details of care processes and follow up after early discharge were not specified apart from the 6 week routine follow up check by the General Practitioner for all patients. The findings should be interpreted with caution.

3.14.3 “Hospital at Home”

Hospital at home care is based on the principle that both nursing and medical care that would normally be provided in hospital is given in the patient’s own home, therefore reducing the length of stay in acute inpatient hospital care. If the hospital at home did not exist then the patient would be admitted to or remain in hospital. This type of care requires health care professionals to take an active part in the patient’s care at home.

A systematic review by Shepperd and Iliffe ⁽¹⁵⁵⁾ defined “Hospital at Home” care as:

“ A service that provides active treatment by health care professionals in the patients own home of a condition that would otherwise require acute hospital inpatient care, always for a limited period.”

Shepperd S and Iliffe S 2005

The first “Hospital at Home” scheme in the UK, was set up in Peterborough in 1978. The aim of this scheme was to reduce pressure on existing hospital facilities and extend choice of care to patients and their families. ⁽¹⁵⁶⁾ Interest in this type of care was shown because of the move towards a primary care led NHS. ⁽¹⁵⁷⁾ and other schemes were set up in Bromsgrove ⁽¹⁵⁸⁾ and South Derbyshire. ⁽¹⁵⁹⁾ General Practitioners retained responsibility for their own patients when they were undergoing ‘Hospital at Home’ care and those involved in the schemes were enthusiastic about alternatives to acute hospital care. The ‘Hospital at Home’ scheme in Peterborough cared for patients with a range of medical and surgical conditions including patients recovering from elective surgical procedures and hysterectomy.

Initial evaluation of these schemes was limited to small-scale surveys and a general overview of the service available.⁽¹⁶⁰⁾ The South Derbyshire scheme, was funded as a waiting list initiative and the model of care was specifically designed to release acute hospital beds and enable 166 extra operations for patients on the orthopaedic waiting list.⁽¹⁵⁹⁾ In this study the initial length of hospital stay for patients receiving standard care following fracture neck of femur was 17 days which was also the total combined length of stay for the “Hospital at Home” group of patients. The author reported that a randomised trial was considered at the start of this scheme, however this was not possible because of funding constraints and timescales for removing patients from the orthopaedic waiting list.

This observational study included a cost analysis and the author quoted financial charges for both types of care giving; £450 for “Hospital at Home” compared with £770 for acute hospital care. However, the use of charges rather than costs does not accurately reflect true costs and a more robust cost effectiveness analysis with the cost of both types of care at the patient level was required to determine more accurate costs.

As “Early Hospital Discharge” and “Hospital at Home” schemes grew in popularity, several observational studies examined the effects of this type of care for patients with a range of medical and surgical conditions.⁽¹⁶¹⁾⁽¹⁶²⁾⁽¹⁶³⁾ A pilot study of the first hundred and two women who were discharged on the third postoperative day following hysterectomy into ‘Hospital at Home’ care in the Peterborough scheme was conducted to test the feasibility of hospital at home care for this type of condition.^{(51) (164)}

3.14.4 Systematic review of hospital at home following elective surgery

A systematic review of randomised trials of ‘Hospital at Home’ care compared with acute hospital inpatient care searched the Cochrane Effective Practice and Organisation of Care Group (EPOC) specialised register, MEDLINE (1966-1996), EMBASE 1980-1995, Social Science Citation Index 1992-1995, Cinahl (1982-1996), Econlit (1969-1996), PsycLit (1987-1996), Sigle (1980-1995) and the Medical Care Supplement on economic literature (1970-1990).⁽¹⁵⁵⁾ The initial review was updated in 2003 and again in 2005. The objective of the review was to

determine the effectiveness and cost of managing patients in "Hospital at Home" compared with inpatient care.

The selection criteria included randomised trials of "Hospital at Home" care compared with acute inpatient care. Twenty- two trials met all the inclusion criteria. In fifteen of the trials the study populations were elderly medical patients, 4 trials recruited patients following elective surgery and one recruited patients recovering from a hip fracture. Two trials included patients with terminal illness and included a mix of medical and surgical patients. Five randomised trials evaluating the effectiveness of "hospital at home" in patients following elective surgery (some of which have been identified previously) were reported. ^{(34) (37) (153) (165) (166)} The two trials by Shepperd et al and Coast et al failed to detect a difference in mortality between both groups at 3 months follow up.^{(37) (166)} Data from these two studies was not combined because the study by Coast included a mix of medical and surgical patients.

Two trials measuring clinical complications, functional status, quality of life and psychological well being in patients recovering from hernia repair and surgery for varicose veins failed to detect a difference between patients receiving "Early Discharge" and those receiving acute care in hospital. ^{(153) 33) (34)} Patients in "Hospital at Home" care who were recovering from Hip replacement reported improved quality of life from Dartmouth COOP Charts compared with patients undergoing routine hospital care.⁽³⁷⁾ Women recovering from hysterectomy showed no difference in SF-36 health related quality of life, physical functioning score following the procedure in both types of care.

Length of stay data were combined from the two studies of patients recovering from elective surgical procedures.^(37) 152) Significant heterogeneity was observed and the data for women recovering from hysterectomy was removed because this study population differed in terms of age and type of procedure. A greater reduction in length of stay was detected for the other surgical conditions. Meta-analysis revealed a significant increase in the total days of care for patients allocated to hospital at home compared with hospital care.

Four of the trials comparing hospital at home with hospital care reported cost data and three of these trials provided estimates of costs that were not based on collection of data from the patient level for both groups of care. ^{(33) (34)(167)} A direct comparison of the costs was not carried out because of the different methods used to measure and calculate costs.

3.14.5 Evidence of the effects of “Hospital at home” in gynaecology

Shepperd et al ⁽³⁷⁾ compared ‘Hospital at Home’ care with acute hospital care in several randomised groups of medical and surgical patients including; 86 recovering from a hip replacement, 86 from knee replacement, 238 from hysterectomy, 96 elderly medical patients and 32 with chronic obstructive airways disease. This is the only randomised study comparing hospital at home with routine hospital care for hysterectomy in the UK.⁽³⁷⁾ The study showed no significant difference in complications in either group of women following hysterectomy. Sixteen (14%) of the women recovering from a hysterectomy, were allocated to “Hospital at Home” but remained in hospital because of complications, and seven (6%) women in the “Hospital at Home” group were readmitted compared with thirteen (10%) readmitted in the hospital group. The study showed significantly more women undergoing hysterectomy in the hospital at home group reported that they resumed parental responsibilities before being well enough ($p=0.02$).

Women recovering from hysterectomy in the “Hospital at Home” group spent 4.32 days (SD 1.86) in hospital care and 3.11 days (SD 2.64) in ‘Hospital at Home’ care compared with 5.79 days (SD 2.98) in standard hospital care. ‘Hospital at Home’ care resulted in a reduction in the length of hospital stay, however this was offset by an increase in the length of stay in ‘Hospital at Home’ and an increase in the overall length of episode of care. Patients recovering from hip and knee replacement and hysterectomy spent significantly fewer days in hospital care, however, with the addition of their ‘Hospital at Home’ days they received significantly more days of health care. ^{(37) (38)}

An economic evaluation and cost minimisation analysis was conducted alongside this study.⁽³⁸⁾ The cost minimisation analysis found no difference in total healthcare costs for patients recovering from a hip or knee replacement or elderly medical patients. However, the analysis showed that "Hospital at Home" significantly increased healthcare costs for patients recovering from a hysterectomy ($p=0.009$). General Practitioner and carer costs were also assessed and showed that "Hospital at Home" significantly increased general practitioners costs for elderly medical patients ($p=<0.01$) and for those with chronic obstructive airways disease ($p=0.02$). Although, there was no significant increase in General Practitioner's costs for patients recovering from hysterectomy.⁽³⁸⁾

This study used patient dependency scores developed by the hospital nursing and medical staff to reflect the marginal costs incurred during a patient's episode of hospital care. The scores were used to estimate the cost of each day a patient was in hospital in order to reflect the differential use of resources during a patient's inpatient hospital stay. Costs of hospital care including staffing and all other hospital running and capital costs were applied using 1994-95 prices.

Health care costs were significantly increased for women recovering from a hysterectomy, with a difference of £92.39 for those in the "Hospital at Home" scheme compared with acute hospital care. A sensitivity analysis was carried in order to test the robustness of the costs by using a different set of assumptions. The sensitivity analysis reducing the number of "Hospital at Home" days altered the costs of patients recovering from a hysterectomy. A reduction of one day eliminated the cost difference for women recovering from a hysterectomy and a reduction of two days altered the costs making "Hospital at Home" the less expensive option for this patient group. This study showed costs were significantly increased for patients recovering from a hysterectomy and those with chronic obstructive airways disease. This was because the total episode of care between hospital and home was greater than standard hospital care in these groups of patients. Shepperd et al, indicated that the thinking behind the randomised study and cost minimisation analysis of "Hospital at Home" was that such schemes would contain health care costs by reducing the demand for acute

inpatient beds. This was not the case because patients who were discharged early from hospital went home when their care was least expensive. “Hospital at Home” increased the overall duration of care and cost in some groups of patients. The findings suggested that ‘Hospital at Home’ schemes could potentially provide care to patients who would otherwise not be receiving health care. This work concluded that there was little evidence to justify the widespread adoption of “Hospital at Home” on the basis of cost.

3.14.6 Summary of alternative models of care

The controlled studies in this review showed that patients allocated to ‘Hospital at Home’ expressed greater satisfaction with care than those in hospital care. However, more importantly, whilst ‘Hospital at Home’ care resulted in a reduction in the length of hospital stay, this was offset by an increase in the lengths of stay in ‘Hospital at Home’ and an increase in the overall episode of care. The review did not support the widespread development of hospital at home care as a cheaper substitute for acute hospital care. Most of the studies had either inadequate or no cost analysis reported. This highlighted the need for more robust economic evaluation when new models of care are introduced and changes in service are made. The limited value of a range of published cost studies has been recognised by economists who have recommended use of formal guidelines in the conduct of robust and meaningful economic evaluation.⁽¹⁶⁸⁾ The final section examines the literature on methods of economic evaluation in health care.

3.15 Economic evaluation in health care

Interest in economic evaluation in health care has risen and is reflected in the increasing number of published economic studies.⁽¹⁶⁹⁾ As the NHS continues to operate within serious financial constraints it is becoming more accepted by clinicians that the adoption of new technologies should be informed by costs as well as effectiveness.^{(42) (107)} In recognition of these financial constraints, the National Institute of Clinical Excellence (NICE) was established to review evidence on the clinical and cost effectiveness of new products and services. There is an expectation that NICE will provide an efficient prioritisation mechanism to ensure the best use of NHS resources.⁽¹⁷⁰⁾ In support of this

national imperative it has become incumbent on clinicians and researchers to assess the costs of new service developments and changes in care provision. Studies that influence health service delivery should not be a comprehensive measurement of outcomes at the expense of an inadequate consideration of costs. (171)

Economic evaluation in health care addresses the question of whether an intervention or procedure is worth doing when compared with other possible uses of the same resources. Evaluations that involve a comparison of the costs and benefits of alternative treatments can provide useful information to health service decision makers about which treatments represent “value for money”. The quality of information on which to base decisions on the use of health care resources has to be meaningful, robust, and clearly understood by decision makers. In order to support this, economists have outlined the key methodological principles of economic evaluation and set the basic standard required of economic evaluations in health care interventions. The principles of economic evaluation set out by Drummond & Maynard ⁽¹⁷²⁾ are shown in figure 1.

Figure 1.

Principles of economic evaluation

1. The study question and perspective must be clearly stated.
2. The study should involve a comparison of at least two alternatives. The do nothing least costly option and most used option should be considered.
3. All relevant costs and benefits should be identified and appropriately valued.
4. The study should be of significant size to assess significant differences between alternatives.
5. The marginal costs and benefits of alternatives should be valued
6. Future costs and benefits should be appropriately discounted.
7. Detailed sensitivity analysis should be conducted

3.15.1 Standardising methods of economic evaluation

A growing number of economic evaluations in health care have been carried out on a wide range of health care interventions, however, there are gaps in the quality of this work.⁽¹⁷³⁾ The limited value of a range of published cost studies has been recognised by economists who set out a framework for standardising the methodologies for a full economic evaluation.⁽¹⁷⁴⁾

Additionally and in response to the poor quality of economic evaluation in journal submissions to the British Medical Journal (BMJ) the editor set up a working party on economic evaluation to improve the quality of submitted and published work. This group produced guidelines and checklists outlining a framework for conducting economic evaluations.⁽¹¹⁰⁾ The working party concentrated on full economic evaluations; comparing two or more health care interventions and considering both the costs and consequences. The guidelines reflect a broad consensus from the working party and from the wider community of economists whose views on the guidelines were sought and debated at the biannual meeting of the UK Health Economists study group. The use of formal guidelines in economic evaluation was seen as an explicit statement of standards required for a sound economic evaluation.

3.15.2 Framework for economic evaluation

The following section outlines the methodological framework for a full economic evaluation, based on the initial work from the guidelines for authors and peer reviewers published by Drummond M F and Jefferson O T on behalf of the BMJ Economic Evaluation Working Party, in 1996. This framework was used to support the relevant design and conduct of an economic evaluation with the RCT as part of the work in this thesis.⁽¹⁶⁸⁾

3.15.3 Study design and economic importance

In an economic evaluation the study design and economic importance of the research question should be outlined. The viewpoint and perspective of the evaluation should be stated and justified to allow judgement of the specific costs and consequences or outcomes of the evaluation. A full economic evaluation should consider all relevant types of costs and consequences of at least two

alternative interventions. This should include both the variable and fixed costs of the intervention or programme and the costs borne by patients and their families, as a result of the intervention and additional costs to society. ⁽¹⁷⁵⁾

3.15.4 Sample size in economic evaluation

In economic studies carried out alongside clinical trials the sample size may have been determined entirely by the clinical endpoints. ⁽¹⁶⁸⁾ In some cases a sub sample is assumed to be adequate for collecting data on resource use but in many cases the variability in resource use data is greater than for clinical parameters and the distribution is often skewed.

3.15.5 Resource estimates and costing methods

Costing involves estimating the resources used and applying unit prices. ⁽¹⁶⁸⁾ The methods for estimating the quantities of resources should be reported separately from the unit costs of the resources used. The currency and price date should be reported and details for any adjustment for inflation or currency conversion should be given. When there are many cost items, reporting should concentrate on the main costs. Estimates of resource use should be based on data on real patients collected either prospectively or retrospectively from medical records. Drummond et al ⁽¹⁶⁸⁾ specifically discouraged the use of 'expert panels' to estimate resource quantities as this may provide inaccurate estimates or specify the resource use for ideal care rather than actual resource use in practice. Prices of resources can be obtained from finance departments but charges can differ from real costs and the extent to which the use of charges may bias results should be reported.

Interventions or procedures can be costed at marginal or average costs. Although the marginal costs may be considered superior because they are the additional costs of changes in the production of a new service, Drummond indicated there were benefits in the use of both. ⁽¹⁶⁸⁾ Marginal costs may be more relevant to local managers, whereas average cost may be more relevant to wider populations. An example of this can be found in national screening policies where average costs may be more appropriate because they reflect the true variable costs of services provided in a large number of facilities. The dates of both the estimates and

resource quantities should be made clear along with details of any adjustments to costs.

3.15.6 Modelling techniques

Modelling techniques enable an economic evaluation to be extended beyond what has been observed in a single set of observations.⁽¹⁶⁸⁾ Modelling may be required to extrapolate the progression of clinical outcomes such as survival and details of any modelling and justification for this should be given.

3.15.7 Dealing with uncertainty

Briggs et al⁽¹⁷⁶⁾ recognised the importance of the systematic handling of uncertainty in economic evaluation. Without proper consideration of uncertainty, it may be difficult to judge if the economic analysis is robust and meaningful. Uncertainty should be handled by an appropriate sensitivity analysis and the range of values used in a sensitivity analysis must be justified and based on evidence or logic.⁽¹⁶⁸⁾

3.15.8 Reporting results

The generalisability of the study population is important in assessing the results of clinical trials and their suitability for economic evaluations. Attention should be paid to the generalisation of cost estimates since relative prices and redeployment of resources may differ between departments and services. Complex presentation of results from economic evaluation can make interpretation by decision makers difficult and this should be considered when presenting results.^(168,175)

3.15.9 Types of economic evaluation

Economic evaluations in health care have been carried out on a range of health care interventions and the key methodological principles should be followed, whichever form of analysis is used.⁽¹⁷¹⁾ Four main types of economic evaluation in health care were found in the literature including; cost minimisation analysis, cost effectiveness analysis, cost utility analysis and cost benefit analysis.^{(171) (172)} Consideration was given to the appropriateness and type of economic evaluation for use within this study. Current approaches to economic evaluation were examined and the approach of cost consequence was explored in more detail.

3.15.10 Alternative approaches in economic evaluation

The underlying assumptions and concerns with current methods of economic evaluation, have led to changes in the theory and the development of alternative approaches.⁽¹⁷⁷⁾ Current best practice methods including cost effectiveness acceptability curves (acceptable cost per quality adjusted life year gained), net benefit frameworks, and probabilistic modelling are reported by Briggs et al.⁽¹⁷⁸⁾ However, Coast argued that that these methods serve to generate a pseudoscientific aura around economic evaluation which camouflage critical weaknesses in current techniques.⁽¹⁷⁷⁾ Limited understanding and knowledge of decision makers in both economic theory and techniques used has been recognised. This has led to difficulties in interpretation of findings.

The validity of funnelling multiple outcomes into one simplistic outcome, such as the QALY has been examined and the meaningfulness of these complex techniques to decision makers has been questioned.⁽¹⁷⁷⁾ The use of a single outcome for cost effectiveness analysis fails to recognise that decision making involves making judgments about a range of important effects and not just one. Coast⁽¹⁷⁷⁾ argued that this limited approach is likely to be used by those who do not fully understand its basis and decisions may be taken which do not reflect society's objectives or beliefs.

3.15.11 Cost consequence analysis

Many have found the concepts behind economic evaluations difficult to interpret.⁽¹⁷⁹⁾ Recent advances including complex economic modelling techniques and acceptability curves place an even greater burden on decision makers. Coast⁽¹⁷⁷⁾ suggested an alternative to current practice would be to restrict all economic evaluations to using the approach of cost consequences. The cost consequences approach is considered a variant of cost effectiveness analysis, but it does not use the cost effectiveness ratios associated with that technique. This approach allows different options to be contrasted clearly in respect of all relevant costs and consequences.⁽¹⁸⁰⁾ Information about implications for equity, need and the effect on others, such as caregivers, can be presented. According to Coast, the cost consequence approach may more closely meet the needs of decision makers than current practice as it avoids extensive use of inadequate assumptions and may

reduce the raft of difficulties inherent in the vast majority of economic evaluations. A number of other benefits are likely to emerge from this pragmatic approach to economic evaluation, but most importantly a cost and consequence analysis will be less complex, easier to understand, and more likely to influence decision making in practice.

The cost consequence approach was also endorsed by Harwood, who gave examples of the limitations in current economic evaluation techniques.⁽¹⁸¹⁾ Harwood suggested that many economic analyses rely on health gain measurements made at a single time point and this does not recognise that benefits from interventions may wane over time. Also, new health problems can erode previous health gains as is the case in chronic conditions where intervention is an ongoing process and not a discrete event. He rejected ‘funnelling’ of different health outcomes into a single measure and gave examples of the difficulties associated with this referring to the commonly used Euroqol Questionnaire, a global generic quality of life measure and the inability of the instrument to detect gains in two randomised two trials. In one trial he reported falls in health status in elderly women following first eye cataract surgery study where the Euroqol was insensitive to benefits that were apparently self evident.⁽¹⁸¹⁾ The other trial of community based early discharge and rehabilitation scheme for elderly people found gains in basic and extended activities of daily living and patient and carers psychological function, but showed little change in the Euroqol after a year.⁽¹⁸²⁾

Donaldson hinted at the economist’s frustration by the dominant cost per QALY approach. He also endorsed the “willingness to pay” approach. However, more importantly, he raised concern about the use of basic definitions of cost effectiveness analysis and cost benefit analysis in health economics, reporting how their ambiguous use can lead to misinterpretation of the results and more importantly misallocation of resources.⁽¹⁸³⁾

The gold standard for assessing the efficacy of interventions is the randomised double blind controlled trial and transparency in reporting can help decision makers generalise results from one setting to another.⁽¹⁸³⁾ Smith⁽¹⁸⁴⁾ argued that any clinical trial that shows a treatment or procedure is effective, is inadequate

without an economic evaluation. He compared this to a “shop window without prices” and urged that all new treatments or procedures in a health system with limited resources must consider the costs as well as the benefits.

3.15.12 Summary of economic evaluation in health care

Economic evaluations in health care have been carried out on a range of health care interventions and the key methodological principles should be followed, whichever form of analysis is used. ⁽¹⁷¹⁾ Use of a framework and formal guidelines in economic evaluation has been seen as an explicit statement of standards required for a sound economic evaluation. ⁽¹⁶⁸⁾ The cost consequence approach may more closely meet the needs of decision makers than current practice, as it avoids extensive use of inadequate assumptions and the difficulties with this. It has been recognised that such an approach may not earn researchers the same kudos for methodological research or technical capability as current methods, but most importantly a cost and consequence analysis will be less complex, easier to understand, and more likely to influence decision making in practice. Details of the approach and methods used in the economic evaluation are provided in the methods chapter.

3.16 Summary of Literature Review

Examination of the literature has shown a growing body of international evidence of the effect of nurses in chronic disease management, particularly in primary and ambulatory care settings.^{(100) (101) (102)} There was less published evidence on the effect of nurses working in the surgical setting and in gynaecology. Evidence of Specialist Nurses in gynaecology was scant and the gynaecology nursing studies that were found focused on the information needs of women undergoing hysterectomy. The potential role of the gynaecology Specialist Nurse in the provision of health promotion for women was recognised.^{(30) (32)}

A number of methodological difficulties have been reported in evaluations of new nursing roles in the health service. The principal difficulty has been the ability to isolate the effect of the nurse on the outcome of patient care.^{(77) (78)} Definition and measurement of outcomes of care has been problematic because of the heterogeneous nature of nursing practice and the range of different outcomes used

in studies. There has been growing interest in the evaluation of subjective health status as a reliable measurement of outcome. ⁽¹⁸⁵⁾ The benefits of health related quality of life measurement has been shown in evaluative research, particularly in RCTs designed to measure health status before and after gynaecological surgical treatment. The SF-36 has also been shown to be valid and reliable when used test changes in treatment regimes and different types of care provided in alternative conditions or settings. ⁽¹²⁹⁾

Pilot studies of new models of care designed to support shorter post-operative length of stay, including “Early Hospital Discharge” have shown that reductions in the length of hospital stay are possible.⁽³⁶⁾ ⁽¹⁵¹⁾ Literature reporting on the length of stay following gynaecological surgery has shown that reductions in length of stay are condition specific, with shorter stays reported following vaginal and laparoscopic procedures than abdominal surgery. The main focus of research has been on “Hospital at Home”, which has been tested and evaluated following a range of surgical procedures, including gynaecological surgery. There have been no randomised trials of “Early Hospital Discharge” following major gynaecological surgery and only one RCT of “Hospital at Home” care including women recovering from hysterectomy. Evidence of “Hospital at Home” demonstrates a reduction in the length of hospital stay, however, this was offset by an increase in the total length of stay in “Hospital at Home” which led to an increase in the overall episode and costs of care for women undergoing hysterectomy. This literature review identified gaps in the evidence of the effects of Specialist Nurses in the gynaecology setting and in the evaluation of new models of care for patients. Most of the studies found in the literature had either inadequate or no cost analysis reported. This highlighted the need for more robust evaluation of the effectiveness and costs of Specialist Nurses in the provision of care for patients across a range of settings. This includes women undergoing major surgical procedures for a range of benign gynaecological conditions.

Chapter 4 - Materials and Methods

4.1 Introduction

This chapter outlines the procedures and methods that were used in the preparation and conduction of the two studies within the thesis. The studies were designed to answer the research questions and reported in two separate stages.

4.2 Research Questions

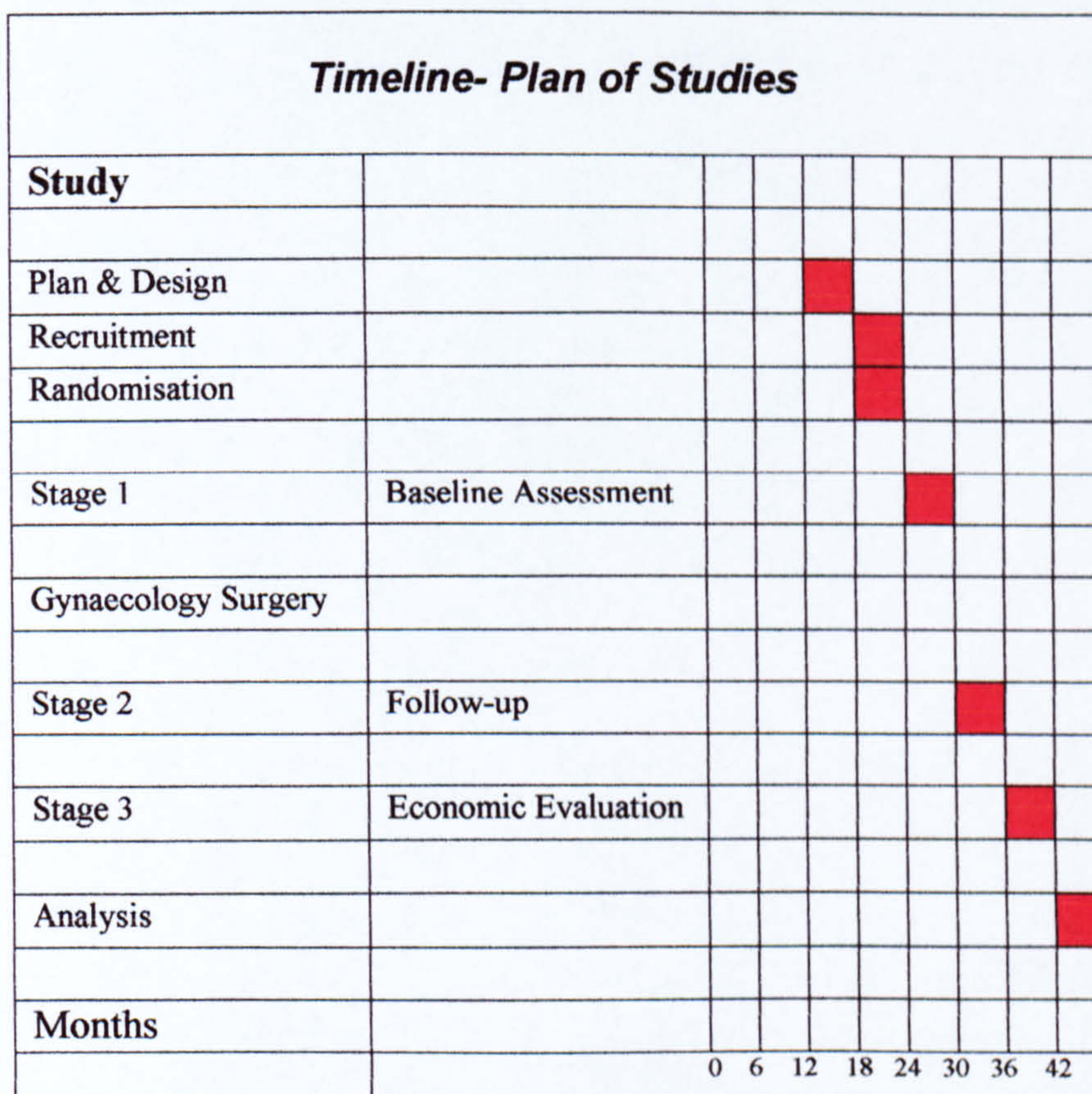
Stage one evaluated the effectiveness of a new model of care supporting early hospital discharge led by a Specialist Nurse and compared this with routine care in gynaecology. Stage two examined and compared the cost of both models of care. The research questions posed were:

- How does the new model of early hospital discharge by a Specialist Nurse in gynaecology impact on patients?
- How does the new model of early hospital discharge by a Specialist Nurse compare with conventional service and routine care in gynaecology?
- What are the costs of the Specialist Nurse service and how do these compare with conventional service and care?

In order to answer these research questions a range of research methodologies were utilised.

4.3 Design and plan of research

The research involved two different methods, including a randomised control trial and an economic evaluation. The randomised control trial was used to compare Specialist Nurse led early hospital discharge with routine care in gynaecology and the economic evaluation was conducted as a sub study of this trial. The key stages of the research and timetable are shown in figure 2.

Figure 2.

4.4 Justification of study design and methods used

A range of research methodologies were utilised within the studies in the thesis. This section outlines the rationale for the study design and choice of methods used in the studies in the thesis.

4.4.1 Randomised Controlled Trial

The objective of the selection of this design of study was to provide information that might help illuminate the roles of Specialist Nurses in the provision of services for patients. The main gaps in the literature pointed to the evidence of the effect of the nurses on patient care and the cost effectiveness of Specialist Nurses in comparison with standard methods of care, which led to the RCT. The studies in the thesis were designed to provide a better understanding of the effect of Specialist Nurses on the outcome and cost of care for patients.

The randomised comparison of a new model of Specialist Nurse supported discharge with routine care in gynaecology at the Western Infirmary Glasgow, during 1999 - 2000. This was made possible because a new model of care led by a Specialist Nurse was introduced for women undergoing major surgery for benign gynaecological conditions. This service model supported shorter hospital stay and promoted the concept of self-care for women. The introduction of a new model of care provided the opportunity to conduct an RCT, which is the gold standard for assessing the efficacy of interventions and the best way to investigate whether cause and effect relationships exist. It was important to test the safety and acceptability of the new model of care for patients and compare this with standard care in gynaecology.

Randomisation is considered the most crucial aspect of a controlled trial.⁽¹⁸⁷⁾ Random allocation of subjects in a study provides them with an equal chance of being assigned to either the experimental or control groups and removes systematic bias within the groups. Randomisation has major advantages firstly it eliminates bias in the assignment of treatment and secondly it determines whether any differences in the outcome of treatment groups may be due to chance alone.⁽¹⁸⁸⁾ Adequate sequence generation is also important in reducing bias as is use of blinding techniques because knowledge of the next random patient assignment could lead to exclusion or direction of the patient to the desired group.

Blinding techniques should also be used to reduce assessment bias, which can occur if subjects and or the research assessors are aware of the treatment allocation. It may not always be possible to blind either the patients or the assessors, depending on the circumstances of the trial and in some clinical situations it is almost completely impossible to blind patients and staff. In this situation careful consideration should be given to how serious any potential bias might be without blinding and sometimes partial blinding by use of independent research assessors can be sufficient to reduce bias in some treatment comparisons.⁽¹⁸⁹⁾

Introduction of the new service model provided the option to conduct an RCT and a range of health outcomes and service related measures were considered for the evaluation. It was recognised that reduction in the length of stay may not be a sufficient indicator of improved outcome from the patients' perspective. Assessment of health status was chosen because the gynaecological literature has shown this to be a reliable and useful measure when comparing the outcome of two different interventions or processes of care.⁽¹⁹⁰⁾ The SF36 questionnaire health related quality of life measure was chosen for use because this instrument has reliably demonstrated the short-term impact of gynaecological procedures including hysterectomy on health related quality of life in women. The SF36 measure has also been shown to be useful to test changes in treatment regimes and different types of care provided in alternative conditions or settings.

4.4.2 Economic Evaluation

Cost effectiveness and value for money also plays a major part in service evaluation and often determines whether a new service or model of care is introduced. The third part of the work in the thesis was an economic evaluation, which was conducted as a sub study alongside the RCT and based on unit costs for 2003 – 2004.

Methodologically sound economic evaluation provides decision makers with information on the cost and consequences of both types of care. Standard practice recommends that all the relevant costs and consequences of any intervention or new model of care be considered. Studies evaluating different interventions and service models should incorporate rigorous economic evaluation methodologies.⁽¹⁶⁸⁾ Consideration of evidence from economic assessment of health care interventions is important. When conducting economic evaluation alongside clinical trials, prior specification of the appropriate economic technique is not usually possible until data on effectiveness and cost are actually available.⁽¹⁹¹⁾ This is because it would require the assumption that the outcomes of the alternatives being compared are equivalent. The final decision to conduct a cost consequence analysis and concentrate on the main cost differences between both groups was taken following analysis of results from stage 1 of the RCT.

4.4.3 Settings for the studies

The Randomised Controlled Trial and Economic Evaluation were set in the Gynaecology Department at West Glasgow Hospitals University NHS Trust. The Trust includes two acute hospital sites covering both the Western Infirmary and Gartnavel General hospital. The Trust serves a population of almost 300 000 people covering all of the West and North West of Glasgow from the city centre to Clydebank in the West and Bearsden and Milngavie in the North West. The studies took place with a Glasgow teaching hospital based within the central belt of Scotland.

4.5 Methods – Randomised Controlled Trial

4.5.1 Study Design

The study design was an RCT including three assessments, one baseline prior to surgery, one post operatively prior to discharge from hospital and the other at six weeks following surgery for benign gynaecological disease. The overall aim of the study was to evaluate a new system of care for women who were undergoing early hospital discharge following major abdominal and or pelvic surgery for benign gynaecological disease and to compare this new model of care led by a gynaecology Specialist Nurse with existing routine care in gynaecology.

4.5.2 New model of care and intervention led by the Specialist Nurse

The new model of care and study intervention was designed to promote self-care and support shorter length of hospital stay for women following major gynaecological procedures. The requirement for medical care during the post-operative recovery period was examined. Detailed discussions between the consultant gynaecologists, Specialist Nurse and local general practitioners took place. This resulted in agreement and production of an integrated care pathway for patients based on the approach of early hospital discharge with self-care and convalescence at home where possible. This process ensured a comprehensive understanding of the role of the Specialist Nurse and the proposed new model of care, and helped achieve a seamless process of care between hospital and home with clear communication between hospital and primary care staff.

The study examined the effects of shorter hospital stay on women receiving the new model of care and compared the new service approach and costs with the conventional service and costs of routine care in gynaecology.

Examination of the effects of early hospital discharge on physical functioning and other health related quality of life domains of women, was considered important in order to identify any adverse effects on recovery and return to normal following surgery. It was relevant to determine health status in women prior to the intervention and during follow up to examine effects of early and standard hospital discharge practice on women's reported health status.

Cost effectiveness and value for money also plays a major part in service evaluation and often determines whether a new service or model of care is introduced. A decision to conduct an economic evaluation was taken because the cost of care is important, particularly if there are other service priorities and competing demands on resources. The economic evaluation will provide decision makers with information on the cost and consequences of both types of care.

Provision of health information for women was considered a useful outcome measure reflecting a requirement of the shorter stay group and as an indicator of the effect of the role of the Specialist Nurse. The study was specifically designed to compare receipt of information on post-operative recovery and return to normal activities between both types of Specialist Nurse care and routine care. In addition to the information giving role on the effects of surgery, recovery period and return to normal, the effect of the Specialist Nurse in the provision of health promotion was examined because the Specialist Nurse had a dedicated role in the provision of health and lifestyle information for women.

4.5.3 Protocol for Routine Care Group

Routine care included the provision of information on the surgical procedure and what to expect in hospital, information on immediate recovery and when to resume normal activity including standard discharge advice. Routine information and advice about post operative recovery and return to normal activities is shown in Appendix 2. Women in routine care were sent home on postoperative day six

which was standard hospital discharge practice. Women allocated to routine care received standard care in gynaecology as provided by the ward nurses and doctors. This included the provision of standard information and care during immediate postoperative recovery and including the requirement and management of an intravenous infusion. Women were given information about pain control and what to expect of an abdominal wound including the presence of surgical drains and urinary catheters. Expected timescales for return of normal bladder and bowel function with and resumption of oral fluids and diet were given. Advice and treatment of constipation was given as prescribed. Early postoperative mobilisation was encouraged and women were advised about the risks and treatment in the prevention of deep venous thrombosis. Women may have been given specific advice on HRT and on Smoking Cessation although this was not routine for all women.

4.5.4 Information for women on return to normal activities

In addition to advice and care during immediate postoperative recovery women were also given information about return to normal activities following surgery and during convalescence. Details of the specific information on return to normal activities which was given to women in both groups is outlined as follows:

4.5.5 Advice on housework/ heavy lifting and exercise

Women were advised to rest and avoid heavy housework duties for one to two weeks after surgery. Advice was given to avoid heavy lifting and strain on both the abdominal and pelvic muscles after surgery. The information given included the avoidance of certain heavy physical tasks such as moving furniture. Advice was given to avoid strenuous exercise and strain on the abdominal and pelvic muscles. Women were advised to start with gentle tasks and gradually increase their level of activity as they felt able.

4.5.6 Advice on resumption of sexual activity

Advice given on the resumption of sexual activity was dependent on pain or presence of bleeding and wound. Women were advised that it was generally considered better to avoid sexual intercourse until any wound sutures were removed and the wound has healed.

4.5.7 Advice on driving following surgery

Women were advised to avoid driving until capable of performing an emergency stop without difficulty or pain. Guidance was that women should also be able to sit comfortable in the car wearing a seatbelt before driving.

4.5.8 Advice on when to return to work

Advice on resumption to work was given dependent on nature of work of the individual woman if it was light or manual/heavy work. Timescales for return to work ranged from six weeks to three months. Women were also advised that their return to work could also depend on advice given to them by their General Practitioner following their period of recovery and convalescence.

Leaflets and information sheets were also given to women in both groups to support the verbal information. In addition to the standard information given by the ward nurses in routine care, as part of the intervention the Specialist Nurse also provided information and advice on health and lifestyle issues.

4.5.9 Protocol for Intervention Group

Women assigned to the study intervention received the same information from the Specialist Nurse on the surgical procedure and what to expect including: immediate recovery and when to resume normal activity as women in routine care. In addition to this the Specialist Nurse assessed women prior to and following surgery and developed a plan for early hospital discharge on post-operative day 2 where appropriate. Women were given specific discharge support information and follow-up arrangements were made. As part of the intervention the Specialist Nurse also gave women information and advice on a range of health and lifestyle issues including smoking cessation, alcohol consumptions, osteoporosis prevention healthy diet and breast self-examination.

4.5.11 Health and Lifestyle Information from the Specialist Nurse

The Specialist Nurse also provided women with a range of information and advice on health and lifestyle issues including smoking cessation, diet and alcohol consumption, osteoporosis prevention, Hormone Replacement Therapy (HRT)

and breast self examination. Detail of the information given to women by the Specialist Nurse on these issues is outlined.

4.5.12 Advice on Smoking Cessation

The Specialist Nurse gave general advice about smoking cessation to women. She advised women of the risks of smoking, paying particular emphasis on the anaesthetic risks at the time of surgery.

4.5.13 Advice on Healthy Diet and Alcohol Consumption

The Specialist Nurse gave women dietary information about general healthy eating and specific dietary advice for weight loss if appropriate. Information on alcohol consumption was given and particular attention was drawn to the recommended number of units of alcohol for women per week.

4.5.14 Advice on Osteoporosis Prevention

Osteoporosis is a condition of the bones in the skeleton. The bones become thinner and less strong with a greater risk of fracture. One in two women are likely to sustain an osteoporosis-related fracture by the age of ninety. There is no known cure for osteoporosis therefore prevention and management of the condition is important. Women are at far greater risk of Osteoporosis than men are. The risk increases with age and early menopause.

The Specialist Nurse gave women dietary advice to ensure a calcium rich diet with a daily intake of green vegetables and Vitamin D to help the body absorb calcium. The body's action of vitamin D can be increased by the action of daylight on the skin.

The Specialist Nurse advised women to keep active by some form of physical activity such as walking, running, cycling, and aerobics. Exercise should be weight bearing and taken daily. In addition women were advised to take care and avoid straining or injury because many cases of osteoporosis are only diagnosed after a fracture. Women were advised to lift correctly, bend knees keeping the back straight and to stop smoking and reduce caffeine intake.

4.5.15 Advice on Hormone Replacement Therapy

The Specialist Nurse advised women about the contraindications to HRT. She discussed the complex issues of breast cancer and the thrombo-embolism risks associated with HRT with women and advised that HRT increases the risk of a venous thrombo-embolism threefold to about 1 in 4,000. The Specialist Nurse advised woman that if they have any doubts or concerns about these conditions that they should discuss with the Consultant or General Practitioner

4.5.16 Advice on Breast Self – Examination

The Specialist Nurse gave information given about the importance of regular breast examination and the main aspect of this advice was to encourage all women to self-breast examine on a monthly basis. The Specialist Nurse advised women what to look for including changes in breast size, change in nipple position, Any obvious lumps or thickening, Blood or discharge from nipple, and anything different their normal appearance.

Advice was about the importance of women becoming familiar with their breasts. The Breast Awareness shower card from Health Promotion Department, Lanarkshire Health Board was issued to all women. .

4.5.17 Training Undertaken by the Specialist Nurse prior to intervention

The Specialist Nurse was a trained gynaecology nurse who was employed as a ‘G’ Grade senior nurse with experience equivalent of “Sister” level.. Prior to implementing the new model of early discharge the Specialist Nurse undertook additional training and completed a theoretical course in the provision of Health Promotion and Health Education at the John Wheatley College. The course comprised of a series of lectures on key components of health education and target areas such as smoking, drinking, healthy eating and exercise. The Specialist Nurse observed the provision of health information to women in the Women’s Health Clinic at the Sandyford Initiative in Glasgow. She also attended a specialist Consultant led Menopause outpatient clinic at the Western Infirmary. During this period of observation and practice she observed the medical and nursing management of women experiencing menopausal symptoms and gained knowledge in the provision of information on both Osteoporosis prevention and

HRT. The Specialist Nurse also received one to one training on breast self examination from a Specialist Breast Nurse (CC) at the Breast Clinic at Stobhill Hospital in Glasgow. This involved both conducting and teaching women the specifics of breast self-examination.

4.5.10 Specialist Nurse Care

Women met with the Specialist Nurse when they were admitted to hospital for surgery. The Specialist Nurse gave women information on her role and the concept of their earlier hospital supported discharge on the 2nd postoperative day following surgery. The Specialist Nurse gave women information on the type of surgical procedure and what to expect including their immediate recovery period, when to resume normal activities and hospital discharge plan. The care given to women by the Specialist Nurse included assessment of their physical condition including their wound, fluid intake and resumption of diet, bowel and bladder function, physical recovery including mobility and return to normal. The Specialist Nurse conducted an assessment of women on their second post operative day this included an overall physical assessment of their condition including assessment of fluid and dietary intake, bladder and bowel function and examination of any surgical wound present. Women were given telephone contacts for the Specialist Nurse and telephoned by the Specialist Nurse on the day after their discharge from hospital. The Specialist Nurse enquired about the woman's general condition including information about fluid intake, diet, bladder and bowel function and wound condition if relevant. The Specialist Nurse offered to visit women at home as required. The gynaecology Specialist Nurse supported discharge protocol can be seen in Appendix 3.

4.5.18 Choice of main outcome measures

A key objective of the study was to assess any change in women's evaluation of their health state. A range of validated Health related quality of life questionnaires were considered for use in the study. The main outcome measure used in the study was quality of life measurement by the SF-36 health survey questionnaire. Secondary measures included; complications, readmission, length of hospital stay, post operative symptom scores, receipt of information on return to normal

activities, lifestyle advice, and satisfaction with hospital care and overall care at 6 weeks follow up.

The SF-36 health related quality of life questionnaire was specifically used to assess physical functioning scores in women following hysterectomy and enable examination of any differences in recovery of women receiving different types of care. Assessment was made four weeks prior to surgery and at six weeks follow up (giving sufficient time to recover from the surgery and get back to normal life).

4.5.19 Short Form 36 (SF-36) health related outcome measure

The Short Form 36 (SF-36) health survey questionnaire was used to measure women's evaluation of their health status before and after surgery. The SF-36 is a multi dimensional general outcome measure that was developed in the USA and adapted for use in the UK.⁽¹⁹³⁾ The SF-36 questionnaire is a shortened version of a battery of 149 health status questions, developed and tested on a population of over 22,000 patients in the USA.⁽¹⁹⁴⁾ The SF-36 questionnaire is a single thirty-six item scale, generating scores for eight multi-item dimensions of health. These include: Physical Functioning, Role Limitation due to Physical Health problems, Bodily Pain, General Health, Vitality (energy/fatigue), Social Functioning, Role Limitations due to emotional problems, and mental health (psychological distress and psychological well being). There is a further un-scaled item asking about health change over the past year. The score for each domain is based on the same scale of 0 to 100 where 0 is the worst possible health status and 100 the best. The SF-36 items and scales were constructed using the Likert method. Rules for scoring items and scales are documented in the SF 36 Scoring Manual.⁽¹⁹⁵⁾ The number of questions associated with the eight health dimensions of the SF-36 are in Table 1.

Table 1 Dimensions of the SF-36 health survey questionnaire		
Area	Dimension	No of question
Functional status	Physical functioning	10
	Social functioning	2
	Role limitations (physical problems)	4
	Role limitations (emotional problems)	3
Well-being	Mental health	5
	Vitality	4
	Pain	2
Overall evaluation of health	General health perception	5
	Health change*	1
Total		36

*This item is not included in the eight dimensions nor is it scored

The validity and reliability of the SF-36 questionnaire has been confirmed in a large number of general population samples and of a variety of patient groups in the USA.^{(139) (138)} Minor modifications to the wording of six items on the SF-36 questionnaire were made to make it acceptable for use in the UK.⁽¹²⁷⁾ Changes to wording in the original questionnaire, included; half a mile' replaced 'block' as a measure of distance, 'pep' replaced 'life' and 'low' was used as an indicator of energy level in the energy and vitality domain, and 'ill' was used instead of 'sick' in the context of susceptibility to ill health. One of the key issues examined by Brazier has been whether a single index measure can be derived from the SF-36 questionnaire for use in economic evaluation.⁽¹⁹⁶⁾ Generic health measures such as the SF-36 are of limited use in the context of an economic evaluation, because they do not indicate the value placed on any change in outcome. The designers of the SF-36 never intended it to be used to derive a single measure of health, although more recently a preference based index has been published.⁽¹⁹⁷⁾ The SF-36 questionnaire can be found in Appendix 4.

4.5.20 SF- 36 health survey data from population studies

Jenkinson and his colleagues produced normative data sets from a large community sample taken from 13042 people in the Oxford Healthy Life Survey.⁽¹²⁸⁾ The authors obtained a 72 % response rate from 9332 people. The study demonstrated high levels of internal consistency and validity and concluded that the SF- 36 was a potentially valuable tool for use in medical research.^(128,185) Table 2 shows mean scores and standard deviation for women by age group.

Table 2 Mean (SD) scores for eight variables of SF 36 for women by age

	Age (years)				
	18-24	25-34	35-54	45-54	55-64
Physical functioning	90.1 (16.4) n=780	92.9 (13.3) n=1274	89.4 (16.1) n=1183	84.8 (18.3) n=917	74.8 (23.5) n=684
Social functioning	85.7 (19.7) n=791	87.1 (18.9) n=1294	86.7 (20.5) n=1210	87.0 (20.8) n=973	85.9 (22.6) n=783
Role Limitations					
Physical:	88.6 (25.5) n=786	86.9 (29.2) n=1294	84.0 (32.0) n=1210	82.4 (32.0) n=960	76.6 (36.9) n=757
Emotional:	78.8 (33.0) n=792	80.6 (34.0) n=1291	80.3 (33.6) n=1207	80.8 (33.6) n=965	83.3 (32.5) n=756
Mental health	70.2 (17.4) n=787	71.6 (15.2) n=1280	71.6 (17.8) n=1187	73.2 (18.2) n=950	74.4 (18.5) n=742
Energy/vitality	59.8 (19.4) n=784	58.3 (19.5) n=1269	58.2 (19.9) n=1200	59.4 (20.3) n=957	59.0 (21.4) n=763
Pain	81.7 (20.8) n=790	82.1 (21.1) n=1299	79.4 (22.0) n=1211	77.4 (22.3) n=965	75.0 (25.1) n=779
General health perceptions	72.1 (20.3) n=787	77.3 (18.5) n=1285	74.1 (20.3) n=1190	73.1 (19.9) n=950	68.0 (22.0) n=747

A series of comparable population studies evaluating the reliability, validity and responsiveness of the SF-36 were conducted in Scotland.⁽¹⁹⁰⁾ Response rates for this study exceeded 75% and results showed that the SF-36 satisfied rigorous psychometric criteria for validity and internal consistency. Reliability of the SF-36 health survey questionnaire was demonstrated in a second population survey of 573 patients attending a gastroenterology clinic in Grampian.⁽¹⁹⁸⁾ These two patient based studies produced similar results for most of the SF-36 dimensions. This work showed that the SF-36 was acceptable to patients, internally consistent and a valid measure of the health status with a wide range of patients.

British studies of the SF-36 quality of life instrument, replicated the findings of the American research. Several SF-36 validation studies demonstrate the value of strategies for interpreting health status based on population normative data.⁽¹²⁷⁾⁽¹²⁸⁾⁽¹⁴⁰⁾⁽¹⁹⁹⁾ This allows individual scores and group averages to be interpreted and compared with normative scores for the general population.

4.5.21 Power calculation

The primary end point used to assess outcome following gynaecological surgery was the difference in the SF-36 scores across its eight health domains. For structural reasons, the sample size could not be estimated from either length of

stay or expected costs. This is because the reduction in length of stay and expected costs are part of the intervention. Published data of mean SF-36 scores in populations with menorrhagia and normal populations were examined to estimate the likely difference than would be expected between pre- and post-operative assessments.

Ruta and his colleagues calculated different degrees of reliability for the SF 36 health domains and estimated study sample sizes required to detect differences in mean SF-36 scores between two randomly selected patient groups.⁽¹⁹⁸⁾ These estimates assume $\alpha=0.05$, two tailed test, power = 0.80 and to detect a difference of 20 points on all eight SF- 36 scales a sample size of at least 64 is required in each group. Statistically significant differences of 20 points are detectable on six of the eight scales with sample sizes of only 30 patients in each group. Table 3 shows estimates of sample size required to detect a 2-20 point difference in the SF36 questionnaire in change over time between two randomly selected groups.⁽¹⁹⁸⁾

Table 3 Estimates of sample size to detect 2-20 point difference in the SF36 in change over time between two randomly selected patient groups. Ruta et al (1993)				
SF 36 Domains	Number of points difference			
	2	5	10	20
Physical Functioning	2544	407	102	26
Social functioning	2478	397	100	25
Role limitations:				
Role-physical	6408	1026	257	64
Role-emotional	6185	990	248	62
Mental health	1405	225	57	14
Pain	2563	410	103	26
Energy and fatigue	1714	275	69	18
General health	1816	291	73	19

4.5.22 Ethical approval

The study received full approval from the West Glasgow Hospitals Ethics Committee. The ethics submission can be seen in Appendix 5, letter of approval Appendix 6.

4.5.23 Recruitment

Patients were recruited to the study over one year from November 1998 to October 1999. Recruitment for the study took place at the outpatient gynaecology clinics of seven consultant gynaecologists, where women were booked for elective surgery and hospital admission. The clinics were based in the outpatient department of West Glasgow Hospitals University NHS Trust.

4.5.24 Patient consent

Patient consent to participate in the study was sought by the clinic nurse when women were booked for elective surgery and hospital admission by a Consultant Gynaecologist. The women were given a complete explanation of the project by the clinic nurse and afforded the opportunity to ask questions about the research. The women were given a copy of the patient information sheet approved by the West Ethics Committee to read and keep, Appendix 7. Women who agreed to participate were asked to sign the consent form which can be seen in Appendix 8. Consenting women were advised that even though they have agreed to take part in the research that they could withdraw this consent at any time without the need to explain why and without any prejudice to their care.

The women were then passed on to be randomly allocated to either Specialist Nurse supported discharge Group A or routine care Group B. Women were advised that they would be told which group allocation on the day of admission to the ward. Non-consenting and non-eligible women were offered routine care as part of normal practice.

4.5.25 Eligibility for study

Exclusion criteria for the study were developed and agreed. Consent to randomisation was sought from all women who were booked for elective Gynaecological abdominal and or pelvic surgery unless:

1. They lived more than 25 Miles (40km) away from the hospital
2. They did not have telephone access at discharge destination
3. They had another major illness, which was likely to dominate the pattern of care, for example advanced cancer, renal failure.

4. Presence of significant physical and or social barriers as determined through professional assessment by Consultant and or Nurse.

All women attending the general gynaecology clinics in West Glasgow Hospitals University NHS Trust between November 1998 and June 1999 were assessed for potential eligibility for study. Eligibility was assessed by a standard history taking assessment, which was carried out by the clinic nurse. Appendix 9. All women (consenting or not) were put through the eligibility assessment to determine their eligibility and identify whether they had any of the exclusion criteria listed above.

4.5.26 Randomisation method

Randomisation was based on a computer-generated sequence of random numbers from 1 to 200. This was stored on a personal computer outwith the department. At the start of the study 200 opaque envelopes were made up with the patient number marked on the outside of the envelopes and the randomisation code sealed inside the envelope. At the beginning of the week the list of women for admission was given to the ward clerk. The non-consenting women were removed and the number of patients to be randomised was confirmed. The ward clerk identified the sequential patient numbers to be allocated that week following on from the last number allocated to the study. The ward clerk then randomly allocated a patient number to each sealed envelope. On the day of admission the sealed opaque envelope with the corresponding number was opened to find the randomisation code. The ward clerk opened the envelope and matched the patient name with the number inside the envelope and corresponding randomisation code. The ward admission clerk held the list of study patients and group allocation.

This procedure was followed to ensure that no one concerned with randomising patients could discover to which intervention the next patient would be allocated. Women in the control group had no identifying marks on their records. This was done to maintain the blinded element of the study as failure to use adequately concealed random allocation can distort the effects of care in either direction causing the effects to seem larger or smaller than they are. Randomisation was not

stratified for surgeon or procedure. This is a recognised limitation of the study because such stratification would guard against imbalance between the groups.

4.5.27 Data extraction from clinical record

Demographic details of the women and clinical information on the operation, postoperative complications and length of hospital stay were extracted from the case notes by a coder recorded on a data extraction form (RM). The data extraction form can be found in Appendix 10.

Clinical information was collected at the time of operation, postoperative progress was recorded and assessment was made of wound, bladder function, and the time the patient spent on the gynaecological ward. Follow-up assessment was made six weeks after surgery.

4.5.28 Gynaecology questionnaire

There were no existing validated outcome measures available that could have been used in the study and two further questionnaires, designed by the principle researcher (myself) were used in the study. These questionnaires were compiled to collect the additional information required to allow the research questions to be answered. The format of the questions varied which were kept as short as possible, and included closed questions, open questions and use of rating scales. Overall satisfaction of care was measured as well as information on what women might expect in hospital, expectations about immediate recovery, when to resume normal activities and assessment of lifestyle information and advice.

A pilot questionnaire was conducted with 5 women who were inpatients in the gynaecology ward during November 1998. The questionnaire was checked for validity and reliability. Some modifications were then made to the questionnaire format and the wording of a few questions before use in the main study. The pilot questionnaires can be seen in appendix 11.

4.5.29 Questionnaire administration

The SF- 36 quality of life questionnaire was administered at two time points; approximately four weeks before gynaecological surgery and again 6 weeks later. Two further questionnaires were administered to women. The first questionnaire was administered to both groups on the second postoperative day following surgery. This assessed immediate post-operative recovery and hospital care. Appendix 12. The second questionnaire examined women's recovery and convalescence at home and this was administered to both groups 6 weeks later (giving sufficient time to recover from the surgery and get back to normal life). Appendix 13.

A research nurse (AG) who was blinded to the group allocation administered the questionnaires to women prior to surgery and on postoperative day 2 and at the six weeks follow-up clinic visit. Attempts were made to conceal group allocation and women in either arm of the study had no identifying marks on their case notes. It was difficult for patients to distinguish between the Specialist Nurse and the ward Sister who had similar levels of seniority in the ward and were dressed in the same style of uniform. Although it was not possible to fully blind the patients and the ward staff from the care given in the two different arms of the study.

The clinical record data and the questionnaire response was transferred by the principal researcher from Excel to the statistical package SPSS for windows to allow data analysis.

4.5.30 Statistical analysis

Data from the all of the questionnaires used in the study were entered and analysed using SPSS for Windows (V 10.0). Data from both of the SF-36 questionnaire recorded at baseline and six week follow-up were entered into an Excel spreadsheet. As with all standardised tests, standardisation and of content and scoring is what makes interpretation of the SF- 36 scales possible. The instructions for scoring the SF-36 data, for the eight multi item scales as detailed in the SF-36 Health Survey Manual and Interpretation Guide were followed. The SF-36 items and scales are scored so that a higher score indicates a better health state. After data entry the items were scored in three steps, including item

recoding for the ten items that require recoding, computing scale scores by summing across items in the same scale and then transforming the scale scores to a 0-100 scale. This was carried out in an Excel spreadsheet by using the scoring algorithms outlined in the SF-36 scoring instruction manual. The SF-36 scoring calculations can be seen in Appendix 14. The SF-36 scores were then imported into SPSS for windows (V 10.0) for analysis.

Sometimes respondents left one or more questionnaire items blank although this happened infrequently. One advantage is that a scale score can be estimated even though responses to some items are missing and the scoring manual recommends that a scale score be calculated if a respondent answers at least half of the items in the multi-item scale. This is done by, substituting the respondent's average score from the other completed items in the scale.

Data from the other two questionnaires, administered at hospital discharge and six week follow up, were entered and analysed using SPSS for Windows (V 10.0). Chi-square test was used to compare proportions between groups and data are presented as means and (standard deviations). Parametric tests were used because the sample size in both groups was around 50 and the distribution of the sample means will be approximately normal.

The two-sample t test was used to compare data between the groups and analysis of covariance was carried out to compare the change in mean scores within the groups. The paired t test was used to compare paired data samples within groups. Medians are used to present the cost data, which usually has highly skewed distribution. The Mann Whitney U non-parametric test was used to measure differences in costs between the groups.

In the process of analysing a large number of independent hypotheses tests, each with a significance level selected at 5%, then even in the absence of any real effects, some of the tests would be significant by chance. This problem becomes more likely with the larger the number of tests. This effect is the result of a type

one error and a simple method of correcting for this is the Bonferroni correction.⁽²⁰⁰⁾ The basis of the correction requires that instead of a significance level based on a p-value <0.05 for any one of the tests, it should be adjusted to a p-value of <0.01 . In effect this means that it is more difficult to demonstrate statistically significant results when multiple analyses are being performed. In the analysis undertaken in this thesis this correction was not undertaken. However, in order to take into account of its effect, p-values of borderline significance, for instance p-values of 0.04-0.05 should be interpreted with caution.

4.5.31 Patients and methods

The study sample was made up of one hundred and sixty three consecutive women undergoing elective gynaecological surgery, of this, nineteen women did not meet the study inclusion criteria, twenty-five women refused to take part and eight women had surgery cancelled. One hundred and eleven consecutive admissions for elective gynaecological surgery were randomly allocated to the clinical nurse specialists supported discharge group or to the control group who continued with current routine care. Subsequently five of the women were withdrawn from the study; one had an unexpected malignancy, one was admitted as an emergency to another ward, two women had cardio respiratory disease and surgery was cancelled. One hundred and six women took part in the study. The flow of patients through the study is shown in the CONSORT⁽²⁰¹⁾ statement included in the methods section.

4.5.32 Follow-up Appointment

At 6 weeks following discharge from hospital patients were invited to attend a follow up visit with the consultant and the research nurse at the gynaecology outpatient clinic. A postal questionnaire was sent out with a supporting letter to women who missed the follow-up appointment. The women were asked to return their completed questionnaire responses to the Research nurse in the prepaid envelope supplied. Those who did not respond to the first questionnaire within four weeks were sent a second letter and repeat questionnaire. A copy of the letter to patients can be seen in Appendix 15.

4.6 Methods : Economic Evaluation Cost Consequence Analysis

4.6.1 Background

The overall aim of the RCT was to evaluate a new model of care led by a gynaecology Specialist Nurse and to compare this approach with routine care in gynaecology. The objective of the cost effectiveness analysis was to provide greater understanding of the cost and consequences of the new system of care from the gynaecology Specialist Nurse and compare this with the existing routine care in gynaecology.

The economic evaluation was a sub study of the RCT and the cost consequence approach was taken. The methods used are outlined in this section. The economic evaluation was based on the perspective of the NHS and the costs of the gynaecology department at the Western Infirmary Glasgow during 2003- 2004. The costs of managing women in both arms of the study were measured until six weeks after surgery.

4.6.2 Type of economic evaluation

The type of economic assessment chosen depends on the efficiency question being asked. ⁽²⁰²⁾ The cost consequence approach is considered a variant of cost effectiveness analysis, although it does not use cost effectiveness ratios that are associated with this technique. ⁽¹⁷⁵⁾ A cost consequence approach was chosen for the evaluation because the multidimensional nature of the SF-36 outcomes makes aggregation difficult. This decision was also influenced because of limited manpower available to support the study. It was also felt that there may be little benefit in conducting an extensive costing exercise for small differences in each patient procedure. The decision to concentrate on the main cost differences between both groups was taken following analysis of results from stage 1 and 2 of the RCT.

4.6.3 Data Collection

During the initial inpatient stay, data were collected prospectively on all resources used during the trial. This information was later confirmed by checking the case records for all resource use related to the inpatient stay. This included pre-

operative stay, blood tests, operation details including type of surgery undertaken, operator details, time in theatre, use of prophylactic antibiotics and details of any intra-operative complications, additional surgery and blood transfusions. The triggers for blood transfusion were not recorded. Post-operative length of hospital stay and additional hospital days including data for treating complications or for readmissions were recorded. The resource data collection form used can be seen in Appendix 16.

4.6.4 Disposable theatre items

All theatre procedures carried out in both groups of the study included standard operating packs with reusable instrumentation. No disposable theatre instruments were used in any of the procedures. The main disposable items used in theatre included sutures and latex Foley catheters and the use of these items were similar in both groups of patients undergoing the same procedures with the same operators.

4.6.5 Regimes for postoperative DVT prophylaxis and pain control

Standard regimes for prevention of postoperative Deep Venous Thrombosis (DVT) prophylaxis and pain control were operational for all women undergoing major abdominal/pelvic surgery in the gynaecology department. The DVT prophylaxis regime was taken from the SIGN guideline.^{(203) (204)} All women in both groups were given Calciparine 5000 iu Sub-cutaneously prior to surgery and twice a day for 48 hours. Graduated elastic compression stockings (TED) were fitted pre-surgery for all women.

Postoperative pain control was based on a standard regime of using a Patient Controlled Analgesia (PCA) system with Morphine 50mg in 50ml saline for 24 hours post operatively and Stemetil 12.5mg IM six-hourly for nausea as required. Voltarol PR 50mg was given three times a day for up to seven days and oral Co-codamol was given 4-6 hourly (maximum of 8 in 24 hours) for up to seven days. A small number of women in both groups did not have PCA and were given Cyclomorph 12.5mg IM 4-6 hourly and Stemetil 12.5mg IM for 24 hours. All women had Intravenous fluids for 24 Hours post operatively. In an earlier study and economic evaluation comparing laparoscopic hysterectomy with Abdominal

Hysterectomy in the same unit found no difference in the use and cost of morphine analgesia.⁽¹⁴⁸⁾

It was considered appropriate to concentrate on the main cost differences between both groups because the group characteristics, principal operations, operators, theatre supplies used, standard regimes for heparinisation and post operative pain control and complications were similar in both groups.

4.6.6 Assessment of main costs

The cost evaluation focused on the main differences between both groups of women in the study. The main differences found between the groups was the length of hospital stay and the input from the Specialist Nurse which included visiting patients at home. There were other smaller differences between the groups including intravenous antibiotic therapy and blood transfusions. These were included because of the high nature of their cost. The costs of consultation with the General Practitioner were included and examined because of the potential burden of transferring the costs of care from the hospital to the community as a result of the shorter hospital stay of women in the Specialist Nurse group.

All resource use was valued using 2003 - 2004 prices. The cost of a day in hospital was calculated from the published costs from the Scottish Health Service Costs Book Manual 2003/04 ⁽²⁰⁵⁾ for inpatient gynaecology in the Western Infirmary. The costs of antibiotics, blood transfusions, consultation with the General Practitioner and cost of the clinical nurse specialists including travel incurred by visiting patients at home were calculated. The costing methods and processes used in the application of the costs for each woman in the study are outlined.

4.6.7 Costing methods

The published costs from the Scottish Health Service Costs Book Manual 2003/04 ⁽²⁰⁵⁾ were used to calculate the cost of a day in hospital. The Costs Book Manual provides financial and related activity information in sets of published tables. The information in the manual is primarily derived from Scottish Financial Returns (SFR's), which are completed as part of the annual accounts cycle. The manual

provides guidance on the completion of the Cost Book SFR'S to ensure consistency and facilitate meaningful comparisons across the NHS in Scotland.

The Cost Book Manual provides direct medical and indirect costs of a hospital inpatient day by speciality, for all Scottish hospitals. This is based on the average number of staffed beds and average bed occupancy. The costs are presented as total direct costs and total allocated costs and together form the total gross cost of an inpatient day weighted by the number of admissions, on a hospital based specialty basis.

4.6.8 HCHS pay and price inflation

Hospital and Community Health Services (HCHS) pay and price inflation index was used to inflate costs to 2003-04 prices where required during the cost calculations. The HCHS is a weighted average of two separate inflation indices, the pay cost index (PCI) and the health service cost index (HSCI). The pay cost index (PCI) and health service cost index (HSCI) are weighted together according to the proportion of hospital and community health service (HCHS) expenditure on each. This provides a Hospital and Community Health Services (HCHS) combined pay and prices inflation. (HCHS) pay and prices inflation figures are available from 1975-1976 to 2003-2004.

4.6.9 Process of application of costs

The costs of the length of hospital stay, antibiotics, blood transfusions, and consultation with the General Practitioner were calculated and applied to all women in the study based on 2003- 2004 prices. The additional costs of the salary of the clinical nurse specialists including travel were calculated and applied to women in the Specialist Nurse Group. The processes used in the application of the costs for each woman in the study is outlined and details of the costs, values and calculation processes are reported for each of the main costs included in the evaluation.

4.6.10 Cost of a day in hospital in Gynaecology at the Western Infirmary

The cost of a day in hospital was obtained from the Scottish Health Service Costs Book Manual 2003/04.⁽²⁰⁵⁾ This cost was calculated by taking and adding the Western Infirmary inpatient gynaecology direct medical cost per case with the allocated 'hotel' cost per case and then dividing this total figure (known as the gross cost per case) by the total length of hospital stay to give a cost per inpatient day. The cost per inpatient day in gynaecology at the Western Infirmary of £801.00 was obtained from the Scottish Health Service Costs Book Manual 2003/04. This cost was then multiplied by the length of hospital stay of each woman, to give the total cost of hospital stay for each woman in the study.

4.6.11 Cost of antibiotic therapy

A range of antibiotics were used and given to women in both groups. There was no standard antibiotic regime in place and the rationale for antibiotic use was determined by the individual Consultant. All intravenous and oral antibiotics including prophylactic doses were recorded in both groups of women. A single set of unit costs for IV and Oral antibiotics based on 2003 - 2004 prices was applied to the antibiotic use of each woman who received antibiotics in the study. This included the costs of prophylactic intravenous antibiotics were given as one bolus dose prior to surgery and other Intravenous antibiotic treatment given to women whilst in hospital. A range of intravenous antibiotics was given to women in both groups of the study including; Augmentin 1.2g, Flagyl 500mg, Cefuroxime 1.5g, and Cefotaxime 1g. The intravenous antibiotic costs for each are for these drugs were calculated for a 24 hours period and are shown in Table 4.

Table 4 Intravenous antibiotic costs at 2003/04 prices (including VAT)

Drug	Dosage	Times a day	Cost per vial	Cost per 24 hours
Augmentin	1.2g	3	£3.05	£7.05
Flagyl	500mg	3	£0.51	£1.18
Cefuroxime	1.5mg	3	£2.82	£6.52
Cefotaxime	1g	2	£5.63	£9.80

Intravenous prophylactic antibiotics were given as one bolus dose in the operating theatre. Intravenous antibiotic treatment was usually given for a 24hour period

and then switched to oral antibiotic unless otherwise stated. The costs were calculated and applied for each women based on the duration of treatment specified in the prescription in the patient’s drug kardex.

The range of oral antibiotics given to women in both groups of the study included; Augmentin 375mg tid Flagyl 400mg tid, Cephalexin 500mg tid, Flucloxacillin 500mg QID, Trimethoprin. The oral antibiotics costs are shown in Table 5.

Table 5 Oral antibiotic costs at 2003/4 prices for 7 days (including VAT)			
Drug	Dosage	Times a day	Total Cost per 21 tablets
Augmentin	375mg	3	£3.53
Flagyl	400mg	3	£0.65
Flucloxacillin	500mg	4	£2.23
Trimethoprin	200mg	2	£0.41

The costs for oral antibiotics were calculated based on a 7 day course of treatment and applied for each woman as specified in the prescription in the patient’s drug kardex.

4.6.12 Cost of a Blood Transfusion

The cost of a blood transfusion was based on a cost by Varney and Guest ⁽²⁰⁷⁾ who estimated the annual UK cost of a blood transfusion and reported the estimated NHS cost for an adult transfusion of red blood cells at £635.00 in 2001. The HCHS price inflation index was used to inflate the blood transfusion price of £635.00 in 2000-01 to £660.00 based on 2003-04 prices a shown in Table 6.

Table 6 HCHS price inflation index used to inflate cost of a blood transfusion				
Dates	2000-01	2001-02	2002-03	2003-04
Cost of Transfusion	£635.00			£660.00
% Increase		0.1%	1.3%	2.5%
This cost was applied to each blood transfusion given to women				

£635.00 by 0.1% for 2001-02, by 1.3% for 2002-03 and by 2.5 % for 2003- 04 to obtain the cost of £660.00 for a blood transfusion in 2003-04. This cost was applied to each blood transfusion received by women in the study.

4.6.13 Salary cost of the Specialist Nurse

The salary cost of the Specialist Nurse was calculated on the basis of G grade. This was a new post and post holder and the salary was taken at the mid point G grade of Nursing and Midwifery Staff, Whitley Salary Scale for 2003-2004. The G grade salary costs were applied for a period of 8 months, to cover the Specialist Nurse throughout the duration of the study. The mid point salary cost of a G grade nurse for eight months was £21,597, this cost was then divided by the total number of women in the Specialist Nurse group to achieve a cost per woman. Salary cost £21,597 divided by 52 women gave a cost of £415.00 per woman in the Specialist Nurse group. This was applied to all women in the Specialist Nurse group.

4.6.14 Travel costs of the Specialist Nurse

The cost of travel for the Specialist Nurse was calculated and applied to each woman on the number of visits made. This was based on a standard car user of 1100 engine size with a mileage rate of 43 pence per mile in 2003-04. Travel costs were based on mileage incurred during visits to patients at their home address. Mileage included travel to patient address from the Western Infirmary and return journey back to Western Infirmary base. These costs were calculated and applied for each visit made by the Specialist Nurse to women at home.

4.6.15 Cost of a GP consultation

The cost of the number of consultations with the GP was calculated for all women in the study. The literature demonstrates substantial variability in the methodology regarding the cost of a GP consultation. Graham and McGregor reported the mean cost of a 10 minute GP consultation expressed in terms of 1995-96 figures as £6.90 +or- 2.73. ⁽²⁰⁸⁾

This cost was taken and the Hospital and Community Health Services (HCHS) price inflation index was used to inflate the cost for a ten minute GP consultation cost to 2003- 2004 prices as shown in Table 7.

Table 7 HCHS price inflation used to inflate the cost of a GP consultation

Dates	1995-96	1996-97	1997-98	1998-99	1999-00	2000-01	2001-02	2002-03	2003-04
Cost- General Practitioner Consultation	£6.90								£10.72
% Increase		1.5%	0.4%	2.5%	1.2%	-.3%	0.1%	1.3%	2.5%

HCHS price inflation index was used to inflate the GP consultation cost with costs of £6.90 in 1995-96 by 1.5% for 1976-97, by 0.4% for 1997-98, by 2.5 % for 1998- 99, by 1.2% for 1999-00, by -.3% for 2000-01, by 0.1% for 2001-02, by 1.3% for 2002-03 and by 2.5% in 2003-04 to obtain the cost of £10.72 for a ten minute GP consultation in 2003-04.

The cost of £10.72 was used to calculate the cost of a visit to the General Practitioner in both groups of women in the study. The cost of £10.72 was multiplied by the number of visits to the GP to obtain the total cost per woman. A small number of women in both groups were visited at home by the GP or seen at the Out of Hours emergency service. As the numbers were small and evenly spread across both group these visits were not included in the analysis.

4.6.16 Statistical analysis

Data for each unit of resource use were entered and analysed using formulae calculations in Excel for windows. These data was then transferred into SPSS for Windows (V 10.0) for statistical analysis.

4.6.17 Sensitivity Analysis

Sensitivity analysis was used to test the robustness of the results to changes in the assumptions made in this study. The systematic handling of uncertainty in economic evaluation is an important area that remains methodologically under developed.^{(176) (178)} Sensitivity analysis is not a single approach and can take a number of different forms. Two different approaches to sensitivity analysis were undertaken in this economic evaluation. The first analysis was based on the assumption that the Specialist Nurse group may, in time, either increase or reduce the length of hospital stay by one day and routine care would reduce length of stay

by one day. The second analysis examined the cost of a day in hospital in gynaecology for all other Scottish Hospitals. The cost of a day in hospital in gynaecology in all other Scottish Hospitals was calculated in the same way as the Western Infirmary day cost using data obtained from the Health Service Cost Manual for 2003/04. The same assumptions in the study cost analysis were tested with the day cost of gynaecology in all other Scottish hospitals. ⁽²⁰⁵⁾

4.6.18 Presentation of the results

Large volumes of data were produced by the research studies and data were analysed using appropriate statistical tests. There were several options for presenting the results and they have been presented in the order that the studies have been described in this chapter.

Chapter 5 Results – Randomised Controlled Trial

5.1 Introduction

The results presented in this chapter are from the randomised trial of a new model of Specialist Nurse supported discharge compared with routine care in Gynaecology at the Western Infirmary Glasgow, during 1999 - 2000.

The primary outcome measure used in the randomised trial was the SF-36 quality of life questionnaire which was administered to women, in both groups, in two stages; prior to surgery, and at six weeks follow up. In addition a questionnaire was administered to women after surgery, before discharge from hospital and at six weeks follow up. In order to answer the research questions, data were collected on demographic and clinical characteristics of the women. Information on symptoms experienced by women in hospital during their post-operative recovery period and operation details, complications, satisfaction and length of hospital stay and costs were recorded. Receipt of information on return to normal activities and lifestyle issues was also assessed.

The results of the economic evaluation and cost consequence analysis carried out alongside the RCT are presented in a separate chapter.

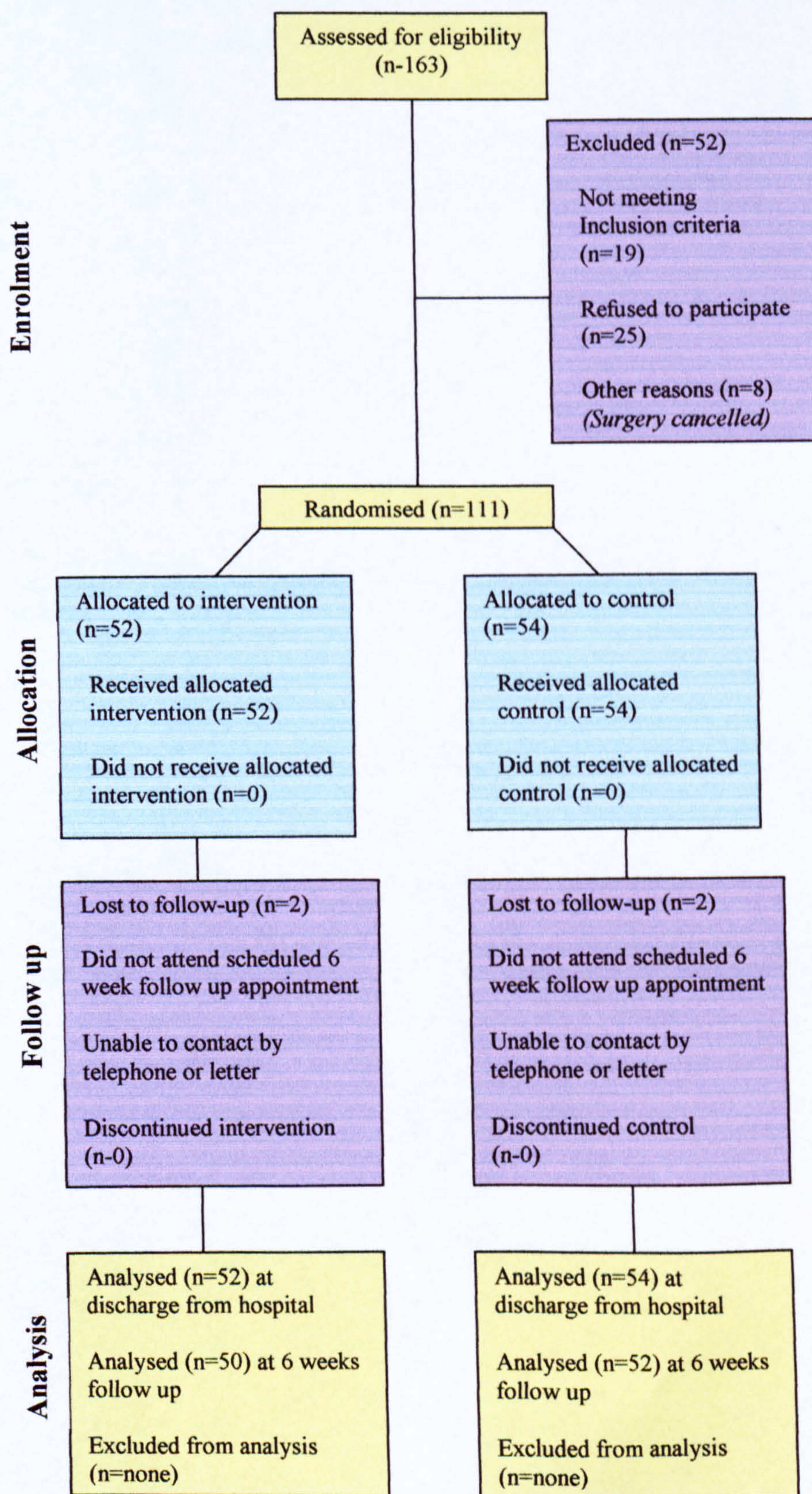
5.1.1 Trial sample

The first woman was recruited to the randomised trial on 11th January 1999 and the final woman was recruited on the 9th June 1999. The study sample was made up of one hundred and sixty three consecutive women undergoing elective gynaecological surgery, of this total, nineteen women did not meet the inclusion criteria, twenty-five women refused to take part and eight women had surgery cancelled. One hundred and eleven consecutive admissions for elective gynaecological surgery were randomly allocated to the clinical nurse specialists group or the control group who continued with current routine care.

Subsequently five of the randomised women were withdrawn from the study; one had an unexpected malignancy, one was admitted as an emergency to another ward, two women had cardio-respiratory disease and surgery was cancelled after admission, and one woman withdrew consent after admission. One hundred and six women completed the study; 52 in the Specialist Nurse Intervention Group and 54 in the Control Group. The CONSORT statement in Figure 3 shows the flow of patients through the study.

Figure 3

Revised template of the CONSORT diagram showing the flow of participants through each stage of a randomised trial (202)



5.1.2 Recruitment to the study

Of the one hundred and sixty-three women who went through the recruitment process to the study, fifty-seven did not take part. Of the fifty-seven women who did not participate, thirty-three women were eligible and twenty-four did not meet the study inclusion criteria. Of the eligible women, twenty-five refused to take part and eight had surgery cancelled. Reasons for non-participation and eligibility for study are shown in Table 8.

Table 8 Eligibility of women recruited who did not take part in the study Total n = 57		
	N	%
Consent refused women eligible	25	44
Surgery cancelled women eligible	8	14
Women withdrawn no longer eligible	5	9
Consent given women not eligible	19	33
Total	57	100

5.1.3 Exclusion from the study

Thirty-two (20%) of all women recruited to the study were excluded. The reasons for exclusion from the study are shown in Table 9.

Table 9 Reasons for study exclusion Total n=32		
	n	%
Live more than 25 miles (40km) away from the hospital	6	19
Do not have telephone access at discharge destination	2	6
Presence of another major illness likely to dominate the pattern of care	5	16
Presence of significant physical and/or social barriers as determined through professional assessment by consultant and/or nurse	11	34
Surgical procedure cancelled/ postponed	8	25
Total	32	100

5.1.4 Questionnaire response rates

The questionnaire completion rate at discharge from hospital was 52 (96%) in the Specialist Nurse group and 54 (95%) in the routine care group. The completion rate at 6 weeks follow up was 93% giving a total of 102 women who completed all parts of the study (50 women in the Specialist Nurse group and 52 women in routine care group). The response rates are shown in Table 10.

Table 10 Response rates from two nurse administered questionnaires at 6 weeks		
	Specialist Nurse (Intervention) n= 52 (n %)	Routine Care (Control) n=54 (n %)
At six weeks follow-up	50 (93)	52 (91)

The overall response rate was good and the main reason for non-response was failure of women to attend a scheduled follow up appointment. Two women did not respond in each group. Subsequent attempts to contact the women by telephone and by post were unsuccessful. Two of the non-respondents were later found to have changed their address.

5.2 Baseline Characteristics of Women

The baseline characteristics of women randomly allocated to Specialist Nurse care when compared with women randomised to routine care were very similar as shown in Table 11. The comparability of these data indicates that randomisation fulfilled its purpose in that any differences in outcome found between the two groups would not be due to group differences in demographic characteristics. The mean age of women was 47 years in the Specialist Nurse group and 46 years in the routine care group. The age range in the Specialist Nurse group was 28-76 years and the age range in routine care was 27-80years.

Table 11 Baseline characteristics of women randomised to Specialist Nurse vs. Routine care					
Characteristic	Specialist Nurse (Intervention) n = 52		Routine Care (Control) n = 54		Chi Square χ^2
Mean age (SD)	46.8	(11.5)	46.4	(12.6)	
	(n)	(%)	(n)	(%)	
Marital Status	40	(77)	39	(72)	$\chi^2 = .975$; df = 3; p = .807
Lives Alone	8	(15)	6	(11)	$\chi^2 = .422$; df = 1; p = .575
Children living at home	29	(56)	28	(52)	$\chi^2 = .164$; df = 1; p = .702
Employed	33	(63)	29	(54)	$\chi^2 = 1.49$; df = 2; p = .473
Takes Regular Exercise	36	(69)	32	(59)	$\chi^2 = 1.14$; df = 1; p = .316
Current smokers	14	(27)	13	(24)	$\chi^2 = .113$; df = 1; p = .825
Drinks alcohol	37	(71)	35	(65)	$\chi^2 = .48$; df = 1; p = .485
Conducts self breast exam	30	(58)	26	(48)	$\chi^2 = .968$; df = 1; p = .339

5.2.1 Demographic characteristics

A postcode analysis by Carstairs index deprivation category was carried out for both groups of women in the study. Four non-Glasgow postcodes were excluded from analysis as shown in Table 12. There was no significant difference in the demographic characteristics of the women in both groups.

Table 12 Postcode analysis by deprivation category						
Deprivation Category	Specialist Nurse (Intervention) n = 48 (n, %)		Routine Care (Control) n = 54 (n, %)		Total both groups	
1 (most affluent)	4	(8)	7	(13)	11	(11)
2	4	(8)	3	(6)	7	(7)
3	4	(8)	4	(8)	8	(8)
4	8	(17)	7	(13)	15	(15)
5	4	(8)	6	(12)	10	(10)
6	16	(32)	15	(28)	31	(30)
7 (least affluent)	9	(19)	11	(20)	20	(19)
Total	48	(100)	54	(100)	102	(100)

For calculation of X^2 for postcode between the groups, Carstairs index 1-7 was grouped as follows: 1 and 2; 3,4,5; 6,7, $X^2 = .37$; $df = 2$; $p = .83$.

5.2.2 Marital Status

There was no difference in the marital status of women in both groups of the study. Forty (77%) of the women in the Specialist Nurse group were married compared with thirty-nine (72%) of women in routine care. The majority of women in both groups were married and there was no significant difference in marital status between both groups, $X^2 = .975$; $df = 3$; $p = .807$ (Table 13).

Table 13 Marital status of women				
	Specialist Nurse (Intervention) n = 52 (n, %)		Routine Care (Control) n = 54 (n, %)	
Married	40	(77)	39	(72)
Widow	5	(10)	5	(9)
Divorced	4	(8)	4	(7)
Single	3	(6)	6	(11)
Total	52	(100)	54	(100)

5.2.3 Parity of women

Eighteen (17%) of the women in the study population were nulliparous. This group was made up of seven (14%) of women in the Specialist Nurse group and eleven (20%) of women in the routine care group. Parity of women was similar in both groups and is shown in Table 14.

Table 14 Parity of women						
Parity	Specialist Nurse (Intervention) n = 52 (n, %)		Routine Care (Control) n = 54 (n, %)		Total both groups	
0	7	(13)	11	(20)	18	(17)
1	11	(21)	6	(11)	17	(16)
2	18	(35)	13	(24)	31	(29)
3	8	(15)	10	(19)	18	(17)
4	4	(8)	9	(16)	13	(12)
5	4	(8)	2	(4)	6	(6)
6	-	-	1	(2)	1	(1)
7	-	-	2	(4)	2	(2)
Total	52	(100)	54	(100)	106	(100)

For calculation of the X² test women with parity of 4-7 were grouped together, X² = 5.0; df = 4; p = .288. There was no significant difference in parity of the women.

5.2.4 Year of last pregnancy

Eighty-eight (81%) of the study population were parous women. The year of their last pregnancy covered a period of 50 years between 1959 and 1999. Table 15 shows the year of last pregnancy of women grouped into ten-year bands from 1950-1999. The distribution of year of last pregnancy was similar in both groups.

Table 15 Year of last pregnancy				
Year of last pregnancy	Specialist Nurse (Intervention) n = 45 (n, %)		Routine Care (Control) n = 43 (n, %)	
1950 – 1959	2	(5)	3	(7)
1960 – 1969	5	(11)	5	(12)
1970 – 1979	9	(20)	10	(23)
1980 – 1989	19	(42)	16	(37)
1990 – 1999	10	(22)	9	(21)
Total	45	(100)	43	(100)

5.2.5 Children living at home

Twenty-nine (56%) of the Specialist Nurse group and twenty-eight (52%) of the routine care group had children living at home with them. Two of the women were living at home with their husband’s children from a previous relationship. There was no significant difference in children living at home between both groups, $X^2 = .16$; $df = 1$; $p = .702$.

Over half of the women in both groups had children living with them at home. The number of children living at home in each group is shown in Table 16.

Table 16 Number of children living at home				
Children at home	Specialist Nurse (Intervention) n = 52		Routine Care (Control) n = 54	
	(n, %)		(n, %)	
0	23	(44)	26	(48)
1	5	(10)	12	(22)
2	17	(33)	11	(20)
3 or more	7	(13)	5	(9)
Total	52	(100)	54	(100)

There was no significant difference in the number of children living at home between both groups, $X^2 = 4.6$; $df = 3$; $p = .199$.

5.2.6 Women who work

Thirty-three (63%) of the women in the Specialist Nurse group were employed in work compared to twenty-nine (54%) women in the routine care group. Five (9.6%) women in the Specialist Nurse group had retired from work, compared to nine (17%) women in the routine care group who were retired. The work status of women is shown in Table 17.

Table 17 Work status of women				
Employment status	Specialist Nurse (Intervention) n = 52		Routine Care (Control) n = 54	
	(n, %)		(n, %)	
Work	33	(63.5)	29	(53.7)
Unemployed	14	(26.9)	16	(29.6)
Retired	5	(9.6)	9	(16.7)
Total	52	(100)	54	(100)

There was no significant difference in the work status of women between the groups, $X^2 = 1.5$; $df = 2$; $p = .473$. Over half of the women in both groups were working and almost a third were not. A small number, less than ten, in both groups were retired.

5.3 Primary outcome SF-36 health status measurement

The Short Form 36 health survey questionnaire (SF-36) was used to assess the self reported health status of women in both groups. The SF-36 scores were assessed prior to gynaecological surgery and again at 6 weeks follow up. The difference in the SF-36 scores across its eight health domains was the primary end point used to assess outcome following gynaecological surgery. This section reports on the baseline SF-36 scores reported by women before surgery.

Analysis of the self-completed SF-36 health survey questionnaire scores is reported in two stages with the first SF-36 questionnaire being completed before surgery and a second SF-36 questionnaire at 6 weeks thereafter. The first analysis examines the baseline scores and initial differences in these scores between both groups of women. Comparisons are also made with SF-36 population normative data and baseline scores of women reported in other published studies.

5.3.1 SF- 36 Health survey questionnaire

The SF-36 questionnaires were completed by all of the women prior to surgery with 106 (52 in the Specialist Nurse Group and 54 in the Control Group). The responses to the self completed SF-36 health survey questionnaires were used to calculate scores for all of the eight health domains in accordance with the formulas for scoring and transforming scales given in the SF-36 Health survey manual ⁽¹⁹⁵⁾ and as previously described in the methods section of the thesis.

The eight SF-36 health domains are: physical functioning, role limitation due to physical health problems, bodily pain, general health perceptions, energy and vitality, social functioning, role limitations due to emotional problems and mental

health which includes psychological distress and psychological well being. The minimum possible score for each domain is 0 and the maximum (best) was 100 for each domain. Details of abbreviations used for the SF-36 domains can be found in Appendix 17.

5.3.2 Stage 1 - Baseline SF-36 scores prior to surgery

Summary baseline statistics are presented in Table 18. Energy and vitality was the lowest scored health domain in both groups with mean score of 45.1 in the Specialist Nurse group and mean score 47.7 in the routine care group. Physical functioning was the highest scored or least affected domain in both groups; mean score 76.4 in the Specialist Nurse group and mean score 75.4 in routine care.

Table18 SF-36 mean baseline scores before surgery Scores range from 0-100 (worst to best).				
SF-36 Baseline scores Pre-surgery	Specialist Nurse (Intervention) n = 50	Routine Care (Control) n = 52	Difference (Specialist Nurse - Routine Care)	Two sample t test P value
	Mean (SD)	Mean (SD)		
Physical functioning	76.35 (23.12)	75.37 (21.79)	.98	.810
Social functioning	71.67 (24.26)	72.10 (22.88)	-.51	.915
Role-physical	58.65 (41.09)	56.48 (41.26)	2.17	.787
Role-emotional	63.44 (43.45)	62.94 (40.83)	.50	.952
Mental health	64.92 (14.03)	67.41 (11.48)	-2.48	.320
Energy/vitality	45.10 (19.77)	47.69 (22.25)	-2.59	.528
Bodily pain	56.08 (22.89)	55.20 (23.45)	.87	.847
General Health	67.12 (19.88)	65.76 (18.43)	1.36	.722

Floor and ceiling effects ⁽²⁰⁹⁾ were evident in scores of role limitation due to physical factors and role limitation due to emotional factors with 26% of women in both groups scoring 0, the lowest possible score in role physical, and 25% of women in the Specialist Nurse group and 20% of women in routine care also scoring 0 for the role emotional health domain. As a result these measures may be less useful as measures of health status in this study

5.3.3 Women’s SF-36 scores compared with population normative data

The SF-36 baseline scores of both groups of women were compared to population normative scores of women aged between 45-54 years and these scores are presented in Table 19.

Table 19 SF-36 comparison mean baseline scores with population normative scores of women age 45 –54 years (Jenkinson C, Coulter A, Wright L, 1993)					
Measure	Specialist Nurse		Routine Care		Population norms
SF-36 baseline scores	(InterventionJ n = 52		(Control) n = 54		women 45-54years
Pre-surgery	Mean (SD)		Mean (SD)		Mean (SD)
Physical Functioning	76.35	(23.12)	75.37	(21.79)	84.8 (18.3)
Social functioning	71.67	(24.26)	72.10	(22.88)	87.0 (20.8)
Role-physical	58.65	(41.09)	56.48	(41.26)	82.4 (32.0)
Role-emotional	63.44	(43.45)	62.94	(40.83)	80.8 (33.6)
Mental health	64.92	(14.03)	67.41	(11.48)	73.2 (18.2)
Energy/vitality	45.10	(19.77)	47.69	(22.25)	59.4 (20.3)
Bodily pain	56.08	(22.89)	55.20	(23.45)	77.4 (22.3)
General Health	67.12	(19.88)	65.76	(18.43)	73.1 (19.9)

The mean baseline scores of women in both groups were lower than baseline population scores of women of similar age.

5.3.4 SF-36 scores comparison with other gynaecological studies

The SF-36 baseline scores of both groups of women were compared with other published scores of women undergoing either medical or surgical treatment for benign gynaecological disease (menorrhagia).

5.3.5 Medical and surgical treatment in UK

One study comparing medical and surgical treatment for menorrhagia by Jenkinson et al measured change in women’s SF-36 scores over time and compared the sensitivity to change of the SF-36 health status measure with a single global health status question. The SF-36 scores of women in the current study are compared and presented with the scores from the study by Jenkinson et al in Table 20.⁽¹⁴²⁾ The physical functioning and role physical scores of women in both groups of the current study were slightly lower and the other scores were comparable with the published scores of women undergoing medical and surgical management of menorrhagia.

A comparison of baseline SF-36 scores with scores from a randomised study evaluating treatment for heavy menstrual loss was also carried out. This study compared medical management with Transcervical Resection of the Endometrium (TCRE) in women with menorrhagia. The mean age of women was 41 years in the medical treatment groups and 42 years in the TCRE group. There was a small difference in the physical functioning scores in this study population. The mental health scores were lower in both groups of women in comparison with the scores obtained in this study both groups of women in the study. Summary SF-36 scores are presented in Table 20. ⁽²¹⁰⁾ ⁽¹⁴²⁾

Table 20 SF-36 mean baseline scores compared with scores from other gynaecological studies

SF=36 baseline scores	Specialist Nurse (Intervention) n=52 Mean (SD)	Routine Care (Control) n=54 Mean (SD)	Cooper et al (1997)		Jenkinson et al (1994)	
			Medical Treatment n=93 Mean (SD)	TCRE n=93 Mean (SD)	Drug Treatment n=189 Mean (SD)	Surgical Treatment n=120 Mean (SD)
Pre Surgery						
Physical Functioning	76.35 (23.12)	75.37 (21.79)	78.88 (20.72)	81.94 (19.38)	86.27 (17.51)	83.76 (19.75)
Social Functioning	71.67 (24.26)	72.10 (22.88)	69.10 (20.98)	69.06 (24.29)	75.54 (21.57)	69.09 (25.00)
Role-Physical	58.65 (41.09)	56.48 (41.26)	54.25 (37.86)	56.72 (39.38)	64.68 (38.32)	60.63 (39.12)
Role-Emotional	63.44 (43.45)	62.94 (40.83)	57.80 (42.10)	53.41 (44.00)	57.14 (41.01)	52.22 (42.94)
Mental Health	64.92 (14.03)	67.41 (11.48)	58.32 (18.27)	59.14 (19.08)	63.47 (19.03)	58.79 (19.04)
Energy Health	45.10 (19.77)	47.69 (22.25)	41.24 (16.84)	41.51 (19.22)	45.11 (21.61)	40.22 (20.73)
Bodily Pain	56.08 (22.89)	55.20 (23.45)	53.80 (24.84)	57.95 (25.16)	62.96 (25.50)	58.06 (25.95)
General Health	67.12 (19.88)	65.76 (18.43)	68.02 (18.85)	65.10 (20.05)	70.75 (21.05)	65.87 (23.71)

5.4 Summary –Baseline SF-36 health survey scores

This section provides a summary of the women's baseline SF-36 health survey scores obtained from the questionnaire administered to women prior to surgery. The follow up SF-36 scores are reported in the next section.

Summary of main findings

- The baseline SF-36 scores in both groups were comparable and there were no significant differences between the scores in both groups of women.
- Energy and vitality was the lowest scored health domain in both groups. Mean score 45.1 SD (19.77) in the Specialist Nurse group and Mean score 47.7 SD (22.25) in routine care.
- Physical functioning was the highest scored or least affected domain in both groups. Mean 76.4 (SD 23.12) in the Specialist Nurse group and Mean 75.4 (SD 21.97) in routine care.
- Floor and ceiling effects were evident in scores of role limitation due to physical factors, and role limitation due to emotional factors. As a result of this these two dimensions may be less useful as measures of health status in this study.
- The mean baseline scores in both groups were lower than baseline population normative scores of women of similar age. However, the baseline scores of women in both groups are in keeping with studies of scores of women with on menorrhagia.

5.5 SF- 36 Follow up Assessment at Six Weeks after Surgery

5.5.1 Stage 2 - SF-36 follow up assessment

The follow up results from the SF-36 questionnaires completed at 6 weeks follow up are presented. This includes analysis of changes in SF-36 scores between both assessments

5.5.2 SF- 36 Health survey questionnaire – Stage 2 follow up scores

The SF-36 follow- up mean scores taken at six weeks after gynaecological surgery and discharge from hospital are reported for both groups of women. These are presented with confidence intervals and difference in scores between routine care and the Specialist Nurse group in Table 21. The two sample t test was used to calculate p values.

Table 21 SF-36 follow-up scores six weeks after surgery				
Scores range from 0-100 (worst to best).				
SF-36 Baseline scores	Specialist Nurse (Intervention) n=48 Mean (SD)	Routine Care (Control) n=51 Mean (SD)	Difference (Specialist Nurse- Routine Care)	Two sample t test P value
Physical functioning	77.40 (22.73)	76.35 (21.42)	1.05	.810
Social functioning	70.10 (25.40)	68.19 (25.06)	1.91	.703
Role-physical	56.50 (38.07)	57.21 (36.83)	-.71	.924
Role-emotional	64.66 (40.68)	65.96 (39.95)	-1.30	.871
Mental health	67.76 (19.45)	70.54 (18.96)	-2.78	.697
Energy/vitality	49.20 (21.03)	52.88 (19.06)	-3.68	.360
Bodily pain	59.88 (24.10)	56.58 (22.56)	3.30	.476
General Health	71.50 (18.43)	70.06 (18.79)	1.44	.697

There were no significant differences in the SF-36 follow up scores in both groups of women.

5.5.3 Follow- up SF-36 scores higher or lower than baseline

The follow up scores of both groups of women were examined for changes showing either higher scores and improved health status or lower scores indicating a reduction in health status.

5.5.4 SF- 36 Health survey questionnaire – Stage 2 change in scores

The individual paired changes in all eight domains of the SF-36 scores from baseline to six weeks were calculated in both groups of women. The mean change in score 95% confidence interval, and the two-sample t test are presented for both groups in Table 22.

5.5.5 Change in SF-36 scores within groups

There was improvement in the follow up paired mean scores in six of the eight SF-36 dimensions, the same six in both groups. The Physical Functioning improvement was small, but the Role Physical and Social Functioning scores were slightly worse in both groups.

Change in the follow up paired mean SF36 scores of women in the Specialist Nurse Group showed improvement in Physical Functioning, Bodily Pain, Role Emotional, Mental Health Energy/Vitality and General Health Perception. The Specialist Nurse Group showed significant improvement in Energy/Vitality $p=0.068$, Bodily Pain $p=0.064$, and General Health perception $p=0.001$.

Change in the follow up paired mean SF36 scores of women in Routine Care showed improvement in Physical Functioning, Bodily Pain, Role Emotional, Mental Health Energy/Vitality and General Health Perception. Improvement in Physical Functioning, Bodily Pain, Role Emotional and Mental Health was small from baseline and two dimensions had p values less than 0.10 Energy/Vitality $p=0.034$ and General Health Perception $p=0.004$.

5.5.6 Change in SF-36 scores between groups

Comparison of the change in pre and post mean SF-36 scores between both groups was carried out by conducting an analysis of covariance. This involved a direct comparison of the post SF-36 mean score using the pre SF-36 mean score as a covariate. There was no significant difference found for each of the eight SF-36 health domain scores between both groups. The Analysis of covariance is shown in Table 23.

Table 22 SF-36 mean change from baseline in follow-up paired scores at six weeks

SF-36 Domain	Specialist Nurse (Intervention) n = 48	95% CI Difference in score	Paired t test	P value	Routine Care (Control) n = 51	95% CI Difference in score	Paired t test	P value
	Mean (SD)				Mean (SD)			
Physical functioning	-1.30 (17.95)	-6.40 to 3.80	.611		-1.25 (13.13)	-4.91 to 2.41		.496
Social functioning	1.34 (19.23)	-4.13 to 6.81	.624		4.21 (23.50)	-2.33 to 10.75		.202
Role-physical	3.00 (31.80)	-6.04 to 12.04	.508		1.44 (34.80)	-8.25 to 11.13		.766
Role-emotional	-2.68 (37.96)	-13.47 to 8.11	.620		-4.44 (39.69)	-15.49 to 6.61		.423
Mental health	-3.44 (14.52)	-7.57 to 0.69	.100		-3.08 (15.41)	-7.37 to 1.21		.156
Energy/vitality	-3.70 (14.03)	-7.69 to 0.29	.068		-5.58 (18.41)	-10.70 to -.45		.034
Bodily pain	-3.42 (12.77)	-7.05 to 0.21	.064		-1.25 (10.86)	-4.27 to 1.77		.410
General Health	-4.88 (9.38)	-7.54 to -2.22	.001		-4.35 (10.39)	-7.24 to -1.45		.004

Table 23 Covariance analysis of change in pre and post mean SF-36 mean scores between the Specialist Nurse and Routine Care Groups

SF-36 Domain	Pre SF36 Score Specialist Nurse (Intervention) n=52	Post SF36 Score Specialist Nurse (Intervention) n=48	Pre SF36 Scores Routine Care (Control) n = 52	Post SF 36 Score Routine Care (Control) n=51	Analysis of covariance P value
	Mean (SD)	Mean (SD)	Mean (SD)	Mean (SD)	
Physical functioning	76.35 (23.12)	77.40 (22.73)	75.37 (21.79)	76.35 (21.42)	.912
Social functioning	71.67 (24.26)	70.10 (25.40)	72.10 (22.88)	68.19 (25.06)	.519
Role-physical	58.65 (41.09)	56.50 (38.07)	56.48 (41.26)	57.21 (36.83)	.834
Role-emotional	63.44 (43.45)	64.66 (40.68)	62.94 (40.83)	65.96 (39.95)	.817
Mental health	64.92 (14.03)	67.76 (19.45)	67.41 (11.48)	70.54 (18.96)	.956
Energy/vitality	45.10 (19.77)	49.20 (21.03)	47.69 (22.25)	52.88 (19.06)	.395
Bodily pain	56.08 (22.89)	59.88 (24.10)	55.20 (23.45)	56.58 (22.56)	.307
General Health	67.12 (19.88)	71.50 (18.43)	65.76 (18.43)	70.06 (18.79)	.706

5.6 Summary SF-36 Follow up assessment at Six Weeks

This section provides a summary of changes in the follow up mean paired SF-36 health survey scores of women in both groups and highlights differences in the SF-36 health status domains between women receiving Specialist Nurse supported discharge and women undergoing routine care.

- There was improvement in the follow up paired mean scores in six of the eight SF-36 dimensions including; Physical Functioning, Bodily Pain, Role Emotional, Mental Health Energy/Vitality and General Health Perception and was the same for both groups.
- In both groups the Physical Functioning improvement was small and the Role Physical and Social Functioning scores were slightly worse which may reflect that women had undergone major gynaecological surgery and were naturally restricted during post-operative recovery and convalescence.
- Change in the follow up paired mean SF36 scores of women in the Specialist Nurse Group showed significant improvement in Energy/Vitality $p=0.068$, Bodily Pain $p=0.064$, and General Health perception $p=0.001$.
- Change in the follow up paired mean SF36 scores of women in the Routine Care Group showed two health domains with p value less than 0.10 Energy/Vitality $p=0.034$ and General Health Perception $p=0.004$.
- Direct comparison of the post SF-36 mean score using the pre SF-36 mean score as a covariate showed no significant difference in each of the scores in both groups.

5.7 Baseline Health Behaviours of Women in the Study

Baseline information on the women’s health behaviours was obtained prior to surgery and is reported in this section. This included information on smoking, alcohol consumption, exercise, breast self-examination, and Hormone Replacement Therapy.

5.7.1 Smoking history of women

There was no significant difference in the number of current smokers in both groups of women with fourteen women (27%) in the Specialist Nurse group and thirteen (23%) women in routine care, $X^2 = .113$; $df = 1$; $p = .825$. The number of smokers in both groups of women was about the same and almost half of the women in each group were either current or previous smokers. The smoking history of women is shown in Table 24.

Table 24 Smoking history of women				
Smoking status	Specialist Nurse (Intervention) n = 52		Routine Care (Control) n = 54	
	(n, %)		(n, %)	
Currently Smoke	14	(27)	13	(24)
Previously Smoked	9	(19)	12	(22)
Never Smoked	28	(54)	29	(54)
Total	52	(100)	54	(100)

There was no significant difference in the smoking history of both groups of women, $X^2 = .199$; $df = 2$; $p = .905$. Table 25 shows the numbers of cigarettes smoked per day by women in both groups.

Table 25 Number of cigarettes smoked per day by current smokers				
Number of cigarettes	Specialist Nurse (Intervention) n = 14		Routine Care (Control) n = 13	
	(n, %)		(n, %)	
5 or less a day	0	(0)	0	(0)
6 to 10	4	(29)	2	(15)
11 to 20	7	(50)	11	(85)
More than 20	3	(21)	0	(0)
Total	14	(100)	13	(100)

Fishers Exact Test (p=.216)

5.7.2 Women who drink alcohol

Reported alcohol consumption was similar in both groups of women with thirty-seven (71%) women in the Specialist Nurse group and thirty-five (65%) women the routine care group drinking alcohol. There was no significant difference in women who drink alcohol between the groups. The frequency of alcohol consumption is shown in Table 26.

Table 26 Frequency of alcohol consumption by women				
Frequency	Specialist Nurse (Intervention)n = 52		Routine Care (Control) n = 54	
	(n, %)		(n, %)	
Most Days	0	(0)	0	(0)
3 to 4 Days per week	3	(6)	6	(11)
1 to 2 Days per week	16	(31)	15	(28)
1 to 2 Days per month or less	18	(35)	14	(26)
No alcohol	15	(29)	19	(35)
Total	52	100	54	100

There was no significant difference in the frequency of alcohol consumption in both groups, $X^2 = 1.9$; $df = 3$; $p = .580$.

5.7.3 Women who take regular exercise

Thirty-six (69%) women in the Specialist Nurse group take regular exercise this compared with thirty-two (59%) women in the routine care group. There was no significant difference between the women who took regular exercise in either group, $X^2 = 1.14$; $df = 1$; $p = .316$.

5.7.4 Women who carry out breast self- examination

Thirty (58%) women in the Specialist Nurse group carried out breast-self examination compared with twenty-six (48%) women in the routine care group. There was no significant difference in women who carried out breast self-examination in both groups, $X^2 = .97$; $df = 1$; $p = .339$.

5.7.5 Women who take Hormone Replacement Therapy (HRT)

Twenty-two women (44%) in the Specialist Nurse group and nineteen women (37%) women in routine care were taking HRT. There was no significant difference in the number of women taking HRT between either group, $X^2 = .590$ df

= 1; p = .442. Sixteen women (32%) in the Specialist Nurse group and twelve women (23%) in the routine care group were taking HRT when they were admitted to the ward, $X^2 = 1.0$; df = 1; p = .313. Six women (12%) in the Specialist Nurse group and seven women (13%) in the routine care group started taking HRT during this admission to hospital.

5.7.6 General health rating compared to other women of same age

There was no significant difference in the general health rating of women in both groups, $X^2 = 3.5$; df = 2; p = .175 as shown in Table 27.

Table 27 General health rating of women.					
General health rating	Specialist Nurse (Intervention) n = 52 (n, %)		Routine Care (Control) n = 54 (n, %)		Total (n, %)
Worse than most	13	(25)	11	(20)	24 (20)
About the same as others	15	(29)	25	(46)	40 (38)
Better than most	24	(46)	18	(33)	42 (40)
Total	52	(100)	54	(100)	106 (100)

5.8 Gynaecological Surgery

All of the women in the study underwent major abdominal or pelvic surgery for benign gynaecological disease. Information on the types of surgery, operation length and the operators was presented. The principle operations were abdominal and pelvic procedures, including Total Abdominal Hysterectomy, Pelvic Floor Repair, and Colposuspension.

There was no significant difference in the surgical procedures undertaken between each group of women, $X^2 = 1.0$; df = 2; p = .606. There was a substantial difference in the number of women losing both ovaries with a bilateral salpingo-oophorectomy being performed in 27 (39%) of women in the Specialist Nurse Group compared with 16 (22%) of those in the control group. This imbalance between both groups is important because it will have a substantial impact on post operative symptoms including treatment of osteoporosis and potential use of HRT. The number and type of procedures undergone by women in each group are shown in Table 28.

Table 28 Operation type undergone by women		
Procedure	Specialist Nurse (Intervention) n = 52 (n, %)	Routine Care (Control) n = 54 (n, %)
Total Abdominal Hysterectomy (TAH)	7 (13)	11 (20)
TAH Bilateral Salpingo Oophorectomy	20 (39)	12 (22)
TAH & R or L Oophorectomy	1 (2)	2 (4)
R or L Oophorectomy	6 (11)	2 (4)
Laparotomy (ovarian cystectomy)	2 (4)	6 (11)
Vaginal Hysterectomy	1 (2)	4 (7)
Colposuspension	3 (6)	3 (6)
Pelvic Floor Repair	6 (11)	11 (20)
Manchester Repair	4 (8)	1 (2)
Sacrospinous Fixation	2 (4)	2 (4)
Total	52 (100)	54 (100)

5.8.1 Operation length

The mean operation length was 55.38 minutes SD (17.57) in the Specialist Nurse group and 58.98 minutes SD (22.85) in the routine care group. There was no significant difference in the length of operation between both groups.

5.8.2 Surgical operators

Six consultant gynaecologists carried out the surgical procedures in both groups. The number of procedures carried out by the consultants in both groups is shown in Table 29.

Table 29 Surgical operator in each group				
Consultant gynaecologist	Specialist Nurse (Intervention) n = 52 (n, %)		Routine Care (Control) n = 54 (n, %)	
Consultant 1	6	(12)	9	(17)
Consultant 2	12	(23)	6	(11)
Consultant 3	6	(12)	13	(24)
Consultant 4	10	(19)	11	(20)
Consultant 5	6	(12)	9	(17)
Consultant 6	12	(23)	6	(11)
Total	52	(100)	54	(100)

5.9 Symptoms reported by women following surgery in hospital

The women were asked to complete two additional questionnaires, one at discharge from hospital and the other at six weeks follow up. The purpose of this was to obtain additional information and compare the post-operative symptoms experienced by women in hospital with symptoms at home following hospital discharge. The aim was to identify any effects of earlier hospital discharge. The post-operative symptoms reported by women whilst in hospital included; pain, disturbed sleep, constipation, wind, mobility restriction and anxiety. There was no significant difference in symptoms reported by women following surgery in both groups as shown in Table 30.

Table 30 Symptoms reported by women whilst in hospital following surgery					
Symptoms	Specialist Nurse (Intervention) n = 52 (n, %)		Routine Care (Control) n = 54 (n, %)		X ²
Pain	46	(88)	48	(89)	x ² = .005; df=1; p=.945
Disturbed Sleep	39	(75)	42	(78)	x ² = .113 ;df=1; p=.821
Constipation	37	(71)	39	(72)	x ² = .015; df=1; p=.903
Wind	8	(15)	9	(17)	x ² = .32; df=1; p=.857
Mobility	8	(15)	9	(17)	x ² = .32; df=1; p=.857
Anxiety	18	(35)	13	(25)	x ² = 1.42; df=1; p=.287

5.9.1 Symptom scores after surgery whilst in hospital

Women were asked to score (on a scale 0-10 from least to most severe) their symptoms experienced following their operation whilst in hospital. The results for post-operative symptoms show that pain had the highest score, followed by constipation and disturbed sleep, in both groups of women. Other symptoms experienced including wind, mobility restrictions and anxiety, were low in both groups. The differences in symptom scores were small between both groups and the mean scores and standard deviations are reported in Table 31.

Table 31 Mean symptom scores of women following surgery before hospital discharge.						
Symptoms in hospital	Specialist Nurse (Intervention) n = 52 (n, %)		Routine Care (Control) n = 54 (n, %)		Difference in score	Two sample t test P value
Score 0-10	Mean (SD)		Mean (SD)			
Pain	5.27	(2.91)	5.63	(2.90)	-.36	.524
Constipation	4.87	(3.85)	5.31	(3.95)	-.45	.554
Disturbed Sleep	4.87	(3.90)	5.20	(3.86)	-.34	.655
Wind	1.25	(3.11)	1.04	(2.61)	.21	.703
Mobility	0.85	(2.30)	0.80	(2.20)	.21	.910
Anxiety	2.19	(3.37)	1.54	(3.02)	.66	.294

The Two sample t test was used to measure differences between the groups. There was no significant difference in the mean symptom scores of women in each group.

5.9.2 How symptoms were dealt with after surgery in hospital

Women were asked to score (on a scale 0-10 from worst to best) how their symptoms were dealt with following their operation whilst in hospital. In both groups the scores on how their symptoms were dealt with in hospital were associated with the severity of their symptoms. Pain management was rated the highest followed by the management of constipation and disturbed sleep. Differences in scores between both groups were small and the means and standard are reported in Table 32.

Table 32 How symptoms were dealt with following surgery in hospital (score 0-10)					
Symptoms in hospital	Specialist Nurse (Intervention) n = 52 (n, %)		Routine care (Control) n = 54 (n, %)		Two sample T test
Score 0-10	Mean (SD)		Mean (SD)		P value
Pain	7.46	(3.26)	7.37	(3.21)	.885
Constipation	5.75	(4.19)	5.15	(3.94)	.448
Disturbed Sleep	4.79	(3.86)	4.76	(3.92)	.969
Wind	1.10	(2.75)	1.30	(3.10)	.726
Mobility	1.00	(2.63)	0.91	(2.33)	.848
Anxiety	2.00	(3.28)	1.76	(3.44)	.713

The Two sample t test was used to measure differences between the groups. There was no significant difference in how symptoms were dealt with in hospital in each group.

5.9.3 Feelings of anxiety reported by women whilst in hospital

Eighteen (35%) women in the Specialist Nurse group and thirteen (25%) women in the routine care group reported feelings of anxiety following surgery whilst in hospital, $X^2 = 1.42$; $df\ 1$; $p=.287$.

Women in both groups were equally anxious about their family at home whilst they were in hospital with nine (17%) women in each group reporting that they were anxious about their family at home, $X^2 = .008$; $df = 1$; $p =.930$.

A small number of the women were anxious about their pets and the security of their home whilst they were in hospital. There was no significant difference in the number of women who had pets at home, this included seventeen (33%) women in the Specialist Nurse group and twenty-four (44%) women in routine care, $X^2= 1.5$; $df = 1$; $p = .214$. Of those women in the Specialist Nurse group with pets at home, 2 (12%) reported being anxious about their pets compared to 5 (21%) of women in the routine care group. Two (4%) women in the Specialist Nurse group and three (6%) women in the routine care group were anxious about the security of their home.

5.10 Effects of surgery and post-operative care in hospital

The effects of surgery in both groups of women; including complications, additional surgery, length of hospital stay, and readmission were examined. Nine (17 %) women in the Specialist Nurse group experienced complications compared with 10 (19 %) of women in routine care as shown in Table 33.

Table 33 Complications following surgery		
Complications	Specialist Nurse (Intervention) n = 9 (n, %)	Routine Care (Control) n = 10 (n, %)
Blood loss (requiring transfusion)	1 (11)	2 (20)
Bladder perforation	0 (0)	2 (20)
Bowel damage	0 (0)	1 (10)
Division adhesions	0 (0)	1 (10)
Wound dehiscence	3 (33)	1 (10)
Wound infection	1 (11)	1 (10)
Vault haematoma	1 (11)	1 (10)
Urine retention	0 (0)	1 (10)
Urinary infection	3 (33)	0 (00)
Total	9 (100)	10 (100)

There was no significant difference in the number of complications between the groups, $X^2 = .026$; $df = 1$; $p = .871$. All of the nine complications in the Specialist Nurse group occurred in women undergoing Total Abdominal hysterectomy apart from one vault haematoma in one woman undergoing a Pelvic Floor Repair. Of the ten complications in the routine care group seven women had undergone Total Abdominal Hysterectomy and the other three women had undergone Pelvic Floor Repair.

5.10.1 Additional surgery

Two (4%) women in the Specialist Nurse group and four (7%) women in routine care underwent additional surgery following complications, $x^2 = .629$; $df = 1$; $p = .428$. Both of the women in the Specialist Nurse group had wound dehiscence and underwent additional surgery for re-suturing of wound during a period of readmission to hospital. The four women in routine care who underwent additional surgery did so at the time of their principal operation, one had repair of bowel damage, one had division of adhesions, two had repair of bladder perforation and of damage to the urinary tract.

5.10.2 Total operation length including additional surgery

There was no significant difference in length of operation, including additional surgery, in both groups: Specialist Nurse group, mean operation length in minutes 56.54 SD (18) and 58.98 SD (22.85) in routine care; Mean Difference -2.44.

5.10.3 Hospital readmission

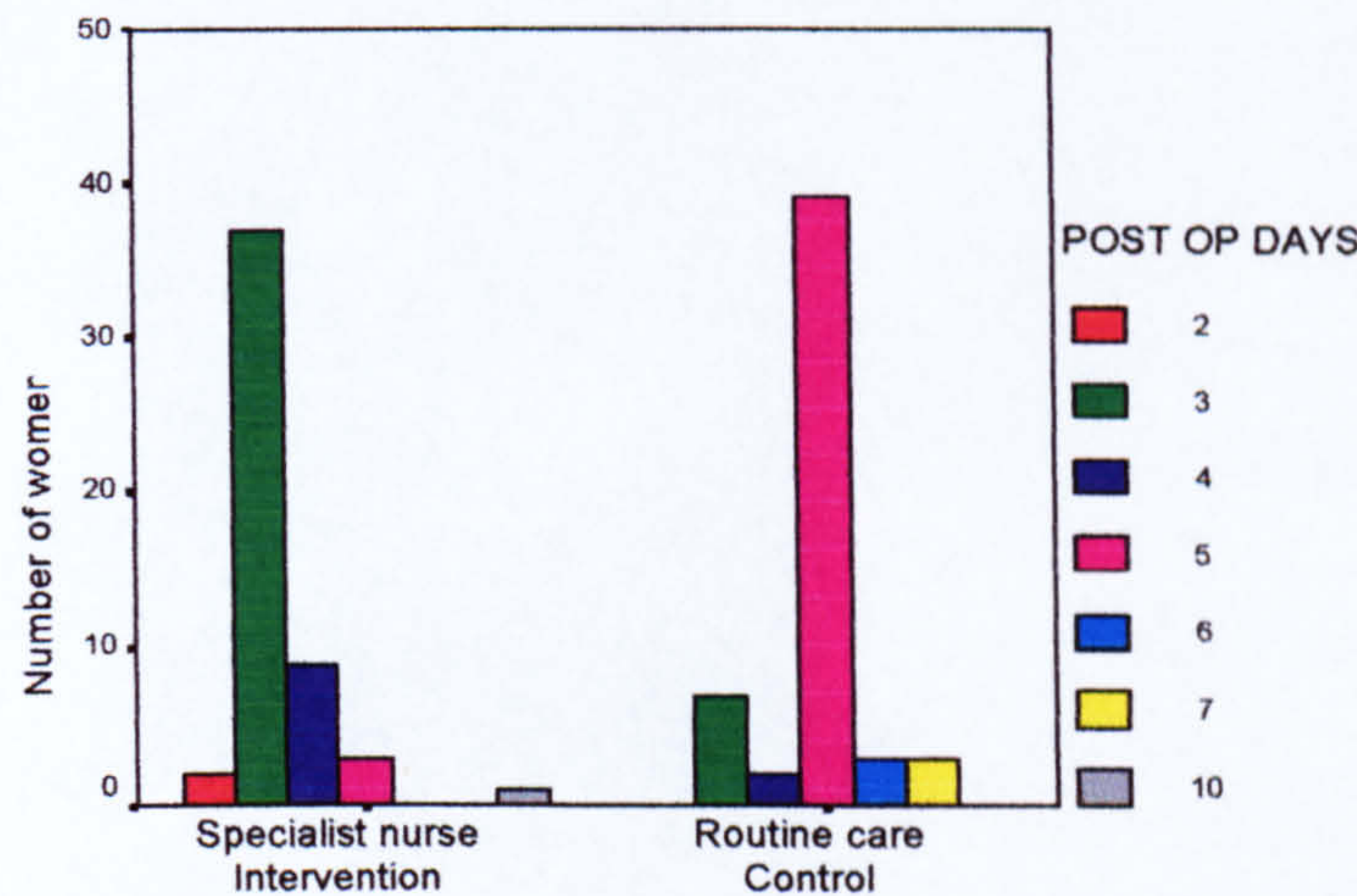
Five (10%) women in the Specialist Nurse group were readmitted to hospital compared with four (7%) women being readmitted from the routine care group, $x^2 = .166$; $df = 1$; $p = .683$.

Of the five women in the Specialist Nurse group who were readmitted, two had additional surgery. This included two women with wound dehiscence who underwent wound re-suturing during a second hospital admission. Of the four women in the routine care group who were readmitted, one had a wound infection, two women had vault haematoma and one was admitted with retention of urine. None of these women had additional surgery.

5.10.4 Length of hospital stay

There was a significant difference in the length of post-operative hospital stay in the Specialist Nurse group in comparison to routine care. Specialist Nurse group mean days in hospital care 3.38 SD (1.12) and 4.87 SD (.91) in routine care. The post- operative length of stay is shown in figure 4.

Figure 4. Post-operative length of hospital stay in days



5.10.5 Length of hospital stay including readmissions

The total length of post-operative hospital stay including additional days from readmissions was significantly shorter in the Specialist Nurse group than in routine care (Table 34).

Table 34 Length of hospital stay (in days) including readmissions				
Length of stay	Specialist Nurse (Intervention) n = 52		Routine Care (Control) n = 54	
	Mean (SD)		Mean (SD)	
Pre-operative stay	1.0	-	1.0	-
Post-operative stay	3.38	(1.12)	4.87	(.91)
Total length of stay (incl readmissions)	4.71	(1.64)	6.06	(1.41)
				.0001

5.11 Information and advice to women following Surgery

The new model of care involved shorter hospital stay, which was supported with adequate patient information and preparation beforehand. Women in both groups were given routine information on return to normal activities following surgery. This included routine post-operative advice about when to resume housework, heavy lifting, driving, sexual intercourse and exercise. In addition the Specialist Nurse gave information and advice on lifestyle issues to women in the intervention group prior to discharge home from hospital. This information included advice on smoking cessation, alcohol consumption, diet, breast self-examination, osteoporosis prevention and HRT. It was not routine practice in routine care to give all women standard information and advice on lifestyle issues. Although individual women may have been told about the effects of hormone replacement therapy, smoking and obesity by ward nurses and doctors, if relevant to their individual condition.

5.11.1 Receipt of information and advice on return to normal activities

Receipt of information and advice on when to resume normal activities was reported by women in both groups. There were significant differences reported by women in Specialist Nurse group about the receipt of information on when to return to normal activities, with the exception of heavy lifting. Receipt of information is shown in Table 35.

Table 35 Information for women on when to return to normal activities

Symptoms	Specialist Nurse group n = 52 (n, %)		Routine Care group n = 54 (n, %)		x ²
Housework	49	(92)	44	(82)	x ² =4.0; df=1; p=.045
Heavy lifting	49	(92)	45	(83)	x ² =3.1; df=1; p=.077
Driving	30	(58)	24	(44)	x ² =20; df=2; p=.000
Sexual intercourse	39	(75)	26	(48)	x ² =13; df=2; p=.001
Exercise	48	(92)	28	(52)	x ² =22; df=2; p=.000

Some women in both groups reported that information on Driving, Sexual intercourse and Exercise was not applicable to them.

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Table 35 Information for women on when to return to normal activities					
Symptoms	Specialist Nurse group n = 52 (n, %)		Routine Care group n = 54 (n, %)		x ²
Housework	49	(92)	44	(82)	x ² =4.0; df=1; p=.045
Heavy lifting	49	(92)	45	(83)	x ² =3.1; df=1; p=.077
Driving	30	(58)	24	(44)	x ² =20; df=2; p=.000
Sexual intercourse	39	(75)	26	(48)	x ² =13; df=2; p=.001
Exercise	48	(92)	28	(52)	x ² =22; df=2; p=.000

Some women in both groups reported that information on Driving, Sexual intercourse and Exercise was not applicable to them.

5.11.2 Information and advice given by different staff

Information and advice on when to resume normal activities was given routinely to all women following surgery by all staff including the ward nurses and doctors. The source of information and advice is shown in Table 36. Not all women answered this question. The number of women responding was 48 in the Specialist Nurse group and 40 in the routine care group. The information given by different combinations of individuals was grouped into “Doctor and Specialist Nurse”, “Doctor and Ward Nurse” and “Doctor, Ward Nurse and Specialist Nurse”.

Table 36 Information given by and advice about when to resume normal activities given by				
Information given by	Specialist Nurse n = 48 (Intervention) (n, %)		Routine Care n = 40 (Control) (n, %)	
Doctor	4	(8)	9	(17)
Specialist Nurse	24	(46)	0	(0)
Ward nurse	7	(14)	16	(30)
Other	1	(2)	3	(6)
Doctor & Specialist Nurse	7	(14)	0	(0)
Doctor & Ward nurse	0	(0)	12	(22)
Doctor & Specialist Nurse & Ward nurse	4	(8)	0	(0)
Total	48	(100)	40	(100)

5.11.3 Amount and quality of information given by different staff

Women were asked to score on a scale of 0-10 from worst to best the amount and quality of information given to them by the ward nurse, doctor, and Specialist Nurse. The two sample t test was used to compare the difference in scores of the ward nurse between both groups and the hospital doctor between both groups. For structural reasons it was not possible to compare the information given by the Specialist Nurse. Table 37 shows mean scores and standard deviations.

Table 37 Mean score from 0-10 on the amount and quality of information given by the ward nurse, Specialist Nurse and the hospital doctor				
Symptoms in hospital	Specialist Nurse (Intervention) n = 52	Routine Care (Control) n = 54	Difference in score	Two sample t test P value
Score 0-10	Mean (SD)	Mean (SD)		
Ward Nurse	7.88 (2.52)	8.93 (1.16)	-1.05	.095
Specialist Nurse	9.63 (1.43)	-----	N/A	-----
Hospital Doctor	8.52 (1.82)	8.28 (1.78)	+0.24	.428

5.11.4 Health and lifestyle information

Forty-nine (98%) women in the Specialist Nurse group reported receipt of information and advice on health lifestyle issues compared with twenty-four (44%) women in routine care, $X^2 = 40.9$; $df = 1$; $p = .0001$. This significant finding reflects lifestyle advice being given to women in the Specialist Nurse group as part of the intervention. However it is not clear how meaningful this information is because both groups were unbalanced in their need for osteoporosis prevention and HRT advice. Women in routine care may have been given specific advice from a range of health professionals. Receipt of lifestyle information and advice to women in both groups prior to discharge from hospital is shown in Table 38.

Table 38 Receipt of information and advice on lifestyle issues prior to discharge from hospital.					
Information and advice on lifestyle issues	Specialist Nurse (Intervention) n = 50 (n, %)		Routine Care (Control) n = 52 (n, %)		X^2
HRT	35	(67)	24	(44)	$x^2 = 5.6$; $df = 1$; $p = .018$
Osteoporosis prevention	40	(77)	9	(17)	$x^2 = 38$; $df = 1$; $p = .0001$
Diet	40	(77)	9	(17)	$x^2 = 38$; $df = 1$; $p = .0001$
Alcohol	20	(39)	1	(2)	$x^2 = 22$; $df = 1$; $p = .0001$
Smoking	19	(37)	8	(15)	$x^2 = 6.5$; $df = 1$; $p = .010$
Breast self- exam	51	(98)	5	(9)	$x^2 = 83$; $df = 1$; $p = .0001$

There were significant differences in receipt of information and advice on lifestyle issues in the Specialist Nurse group on all six parameters including HRT, osteoporosis prevention, diet, alcohol, smoking and breast-self examination. These results demonstrate the planned effect of the Specialist Nurse in the provision of lifestyle information. The significant differences in advice on HRT and osteoporosis prevention, should be interpreted cautiously because both groups were unbalanced in their need for advice regarding HRT and osteoporosis prevention and may reflect in these findings.

5.11.5 Follow information on health and lifestyle issues

Women in both groups indicated that they would follow information and advice on lifestyle issues including HRT, osteoporosis prevention, diet alcohol, smoking and breast self- examination as shown in Table 39.

Table 39 Women who said they would follow information and advice on lifestyle issues prior to discharge from hospital.

Information and advice on lifestyle issues	Specialist Nurse (Intervention) n = 52		Routine Care (Control) n = 54		χ^2
	(n, %)		(n, %)		
HRT	33	(64)	36	(67)	$\chi^2 = 2.3$; df = 2; p = .309
Osteoporosis prevention	40	(77)	43	(80)	$\chi^2 = 2.5$; df = 2; p = .286
Diet	43	(83)	39	(72)	$\chi^2 = 2.8$; df = 1; p = .236
Alcohol	21	(40)	29	(54)	$\chi^2 = 11.6$; df = 2; p = .003
Smoking	21	(40)	15	(28)	$\chi^2 = 17.7$; df = 2; p = .000
Self breast exam	49	(94)	43	(80)	$\chi^2 = 5.3$; df = 2; p = .069

The number of women who said they would follow lifestyle advice on HRT osteoporosis prevention and healthy diet in both groups was not significantly different. There were significant differences in the number of women who said they would follow advice on smoking in the Specialist Nurse group and there was a significant difference in the number of women in routine care who said they would follow advice on alcohol consumption. The number of women in both groups who said they would follow lifestyle advice may give an indication of the relevance of the advice.

5.11.6 Satisfaction with hospital care

Prior to discharge home from hospital the women were asked to rate their satisfaction with hospital care. Women were equally satisfied with hospital care in both groups and satisfaction was high with 85% of women in the Specialist Nurse group scoring in the “very good” and “excellent” categories compared with 79% of women in routine care. Satisfaction with hospital care is shown in Table 40.

Table 40 Satisfaction with hospital care reported by women at discharge from hospital

	Specialist Nurse (Intervention) n = 52		Routine Care (Control) n = 54	
	(n, %)		(n, %)	
Poor	0	(0)	1	(2)
Fair	2	(4)	2	(4)
Good	6	(11)	8	(15)
V Good	14	(27)	16	(29)
Excellent	30	(58)	27	(50)
Total	52	(100)	54	(100)

For chi-square purposes, satisfaction was grouped into poor/fair, good, very good and excellent, $X^2 = 7.39$; df 3; $p = .864$. There was no significant difference in satisfaction with hospital care in both groups of women.

5.12 Summary Stage 1 Post-Operative Hospital Care

This section provides a summary of the effects of surgery including post-operative symptoms in hospital, receipt of information and lifestyle advice. This information was obtained from the questionnaire administered to women after surgery and before discharge from hospital.

Main findings

- The baseline characteristics of women randomly allocated to both groups were very similar.
- There were no significant differences in the principal surgery carried out and the length of operation between both groups.
- Immediate post-operative symptoms, including pain, disturbed sleep, constipation, wind, mobility restriction and anxiety, were similar in both groups of women.
- There was no significant difference in post-operative complications in both groups although the sample was not adequately powered to detect a significant difference. The majority of complications occurred in women undergoing Total Abdominal Hysterectomy in both groups.
- Planned reduction in the length of hospital stay was part of the Specialist Nurse intervention and the length of hospital stay was significantly shorter $p = 0.001$ in the Specialist Nurse group than in the Routine Care Group.

- There was no significant difference in readmission rates to hospital between the groups of women. Five (10%) women were readmitted in the Specialist Nurse Group compared with four (7%) women in the Routine Care Group.
- There were significant differences reported by the Specialist Nurse Group about receipt of information on when to resume normal activities including; housework $p=.045$, driving $p=.000$, sexual intercourse $p=.001$, exercise $p=.000$, and when to return to work $p=.026$, compared with Routine Care.
- There were significant increases in receipt of information on lifestyle advice by women in the Specialist Nurse Group compared with those in Routine Care. This demonstrates the planned effect of the Specialist Nurse in the provision of lifestyle information. It is not clear how meaningful the significant findings for osteoporosis prevention and HRT advice are because there was an imbalance in the number of patients undergoing salpingo-oophorectomy in both groups and their subsequent need for osteoporosis prevention and HRT advice.
- Satisfaction with hospital care was high in both groups with 85% of women in the Specialist Nurse group scoring in the “very good” and “excellent” categories compared with 79% in routine care. Women were equally satisfied with hospital care. There was no significant difference in satisfaction at discharge from hospital in both groups.

5.13 Stage 2 - Recovery at home six-week follow-up

The second questionnaire administered to the women at 6 weeks follow up provided information on women’s symptoms and recovery at home. This information was examined to identify any effects as a result of shorter hospital stay and enabled a comparison of symptoms experienced by women in hospital and home.

5.13.1 Response rate from questionnaire at 6 weeks follow-up

Two women from each group did not complete the questionnaire at six weeks follow up. The questionnaire completion rate at 6 weeks follow up was 93% giving a total of 102 women (50 in the Specialist Nurse Group and 52 in the Routine Care Group).

5.13.2 Preparedness for discharge home

Women were asked to score (on a scale 0-10 from worst to best) how prepared they were for discharge home and their confidence about being able to contact the ward or Specialist Nurse when back at home (Table 41).

Table 41 Prepared for discharge home and confident could contact the nurse				
	Specialist Nurse n = 50 (Intervention) Mean (SD)	Routine Care n = 52 (Control) Mean (SD)	Mean diff (Specialist Nurse - Routine Care)	Two sample t test
Prepared for discharge home from hospital	8.34 (2.51)	8.31 (2.26)	.04	.946
Confident could contact the nurse at any time	9.58 (1.11)	7.02 (4.23)	2.56	.001

5.13.3 Women knew how to contact the hospital following discharge

Detailed information and a dedicated phone number on which to contact the Specialist Nurse following discharge from hospital were given to women in the intervention group but this was not part of routine care. All of the women in the Specialist Nurse group indicated they knew how to contact the Specialist Nurse at

the hospital following discharge. Forty-four women (85%) in routine care indicated that they knew how to contact the hospital following discharge.

5.13.4 Number of times women contacted the hospital

Women in the Specialist Nurse group had significantly more contacts with the hospital than women in routine care, $X^2 = 11.54$; $df = 4$; $p = .021$, This was linked to the fact that these women were given the dedicated telephone number of the Specialist Nurse and were encouraged as part of the intervention to call for advice from the Specialist Nurse as required. Although not part of routine care, women in both groups reported contacting the hospital following discharge. Table 42 shows the number of times women contacted the hospital.

Table 42 Number of times women contacted the hospital				
	Specialist Nurse (Intervention) n = 50 (n, %)		Routine Care (Control) n = 52 (n, %)	
0 (no contact)	18	(36)	33	(63)
Once	21	(42)	15	(29)
More than once	11	(22)	4	(8)
Total	50	(100)	52	(100)

5.14 Symptoms of women at home

The symptoms experienced at home were similar to those reported post operatively in hospital in both groups of women. There were no significant differences in the symptoms reported by women at home in both groups as shown in Table 43.

Table 43 Symptoms experienced by women at home					
Symptoms	Specialist Nurse n = 52 (Intervention) (n, %)		Routine Care n = 54 (Control) (n, %)		X ²
Pain	39	(78)	45	(87)	X ² = 1.2; df=1; p = .305
Disturbed Sleep	30	(60)	29	(56)	X ² = .18; df=1; p = .693
Wound Problem	8	(16)	7	(14)	X ² = .13; df=1; p = .717
Constipation	29	(58)	31	(60)	X ² = .02; df=1; p = .868
Wind	10	(20)	4	(8)	X ² = .32; df=1; p = .088
Mobility	6	(12)	8	(15)	X ² = .24; df=1; p = .619
Anxiety	30	(60)	28	(54)	X ² = .39; df=1; p = .530

5.14.1 Symptom scores of women at home

Women were asked to score (on a scale of 0-10) symptoms experienced at home. Mean scores and standard deviations are reported in Table 44. The Two sample t test was used to assess differences between groups.

Table 44 Mean symptom scores of women at home						
Symptoms at home	Specialist Nurse (Intervention) n = 50		Routine Care (Control) n = 52		Two sample t test P value	
Score 0-10	Mean (SD)		Mean (SD)		95% CI	
Pain	4.38	(3.24)	4.12	(2.99)	-.96 to 1.49	.708
Constipation	3.84	(4.22)	4.15	(4.29)	-1.99 to 1.36	.776
Disturbed Sleep	3.26	(3.58)	2.83	(3.44)	-.95 to 1.81	.535
Wind	1.70	(3.59)	0.67	(2.43)	-.17 to 2.23	.075
Mobility	0.58	(1.84)	0.79	(2.23)	-1.01 to .60	.618
Anxiety	2.72	(3.22)	2.79	(3.29)	-1.35 to 1.21	.927

The follow up symptom scores show that that pain remained with the highest score, followed by constipation and disturbed sleep. There was no significant difference in symptoms experienced by women at home between the groups.

There was a reduction, although not significant, in most of the symptoms reported at home, compared to the symptoms experienced in hospital. Four of the six symptoms measured were reduced at the 6 week follow up assessment, including pain, disturbed sleep, constipation and mobility in both groups. There was a slight increase in symptom of wind in the Specialist Nurse group and a marked increase in anxiety reported in both groups of women.

5.14.2 Change in women’s symptom scores at home

Change in symptom scores taken after surgery in hospital and symptom scores at home following hospital discharge was measured in both groups of women. The mean change in score, 95% confidence interval and paired t test are presented for both groups in Table 45.

Table 45 Change in symptom scores of women from baseline in hospital and at home. Scores range from 0-10 (best to worst)						
	Specialist Nurse (Intervention) n = 49	95% CI	Paired t test P value	Routine Care (Control) n = 51	95% CI	Paired t test P value
	Mean (SD)			Mean (SD)		
Pain	.88 (4.02)	-.26 to 2.02	.128	1.63 (3.96)	.53 to 2.74	.004
Constipation	-2.54 (4.14)	-3.72 to -1.36	.196	-2.87 (4.28)	-4.06 to -1.67	.243
Disturbed sleep	1.70 (4.84)	.33 to 3.07	.016	2.37 (5.26)	.90 to 3.83	.002
Wind	-.60 (3.73)	-1.66 to .46	.261	.21 (3.26)	-.70 to 1.12	.642
Mobility	.26 (1.23)	-8.84 to .61	.140	3.85 (1.71)	-.44 to .52	.872
Anxiety	-.52 (4.77)	-1.88 to .84	.444	-1.19 (4.14)	-2.35 to -3.84	.043

Data was missing for two women one from each group. There was improvement in the follow up paired mean scores in symptoms of pain, disturbed sleep and mobility score, but there was an increase in the symptoms of constipation, wind and anxiety in the Specialist Nurse group. Improvement in disturbed sleep ($p=.016$) reached significance in the Specialist Nurse group.

Symptom scores of pain, disturbed sleep, wind and mobility were improved in routine care but the constipation and anxiety scores were worse. The symptom scores of pain ($p= .004$) and disturbed sleep ($p=.002$) were significantly improved in the control group at six weeks follow up.

The picture of symptom scores in both groups of women, reflect the effects of the surgery and show higher levels of post-operative pain, disturbed sleep, constipation in hospital immediately following surgery than symptoms experienced by women at home. The change in symptoms scores from hospital and home including the highly significant differences in disturbed sleep and pain in the control group show a greater improvement in these symptoms in the control group. The other symptom differences were small and reflect minor changes experienced by women in both groups during their recovery following surgery.

5.14.3 Scores of how symptoms were dealt with at home

Women were asked to score (on a scale 0-10 from worst to best) how their symptoms were dealt with at home following discharge from hospital. Mean scores and standard deviations are reported in Table 46. The Two sample t test was used to measure differences between the groups.

Table 46 Mean score 0-10 How symptoms were dealt with at home.					
Dealt with at home	Specialist Nurse n = 50 (Intervention)		Routine Care n = 52 (Control)		Two sample t test
Score 0-10	Mean (SD)		Mean (SD)		P value
Pain	5.96	(3.78)	5.90	(3.38)	.773
Constipation	4.80	(4.59)	4.62	(4.42)	.848
Disturbed Sleep	3.56	(3.59)	3.17	(3.49)	.583
Wind	1.60	(3.42)	0.67	(2.43)	.079
Mobility	0.70	(2.02)	1.06	(2.68)	.583
Anxiety	2.00	(3.28)	1.76	(3.44)	.990

Scores of how symptoms were dealt with reflected the symptoms scores of the women in both groups and is associated with the severity of symptoms experienced. The highest scores are reported for pain management and constipation followed by disturbed sleep scores. There was no difference in how symptoms were dealt with at home in either group.

5.14.4 Change in how symptoms were dealt at home

Change in scores of how symptoms were dealt with after surgery in hospital and at home following hospital discharge were assessed. Change scores are presented for both groups in Table 47.

Women in both groups scored how symptoms were dealt with at home. Women in both groups reported higher scores for pain management and how disturbed sleep was managed at home. This may reflect lessening symptoms with recovery at home. Neither group showed any other significant differences in the change scores of how symptoms were dealt with in hospital and at home.

Table 47 Change in how symptoms were dealt with from baseline in hospital and at home. Scores range from 0-10 (best- worst).

(Score 0-10)	Specialist Nurse (Intervention) n = 49	95% CI	Paired Sample t test	P value	Routine Care (Control) n = 51	95% CI	Paired Sample t test	P value
Pain	Mean (SD) 1.48 (4.34)	.25 to 2.71	.020		Mean (SD) 1.58 (4.65)	.28 to 2.87		.018
Constipation	1.08 (6.18)	-.68 to 2.84	.222		.38 (6.07)	-.131 to 2.08		.650
Disturbed sleep	2.12 (4.65)	.80 to 3.44	.057		1.69 (4.78)	.36 to 3.02		.048
Wind	-.66 (3.43)	-1.64 to .32	.180		.48 (3.74)	-.56 to 1.52		.358
Mobility	.14 (1.62)	-.32 to .60	.543		-.12 (2.16)	-.72 to .49		.701
Anxiety	-.74 (4.38)	-1.98 to .50	.238		-.96 to 4.46	-2.20 to .28		.126

5.14.5 Time home from hospital

The women were asked about their length of stay in hospital. Forty (80%) of women in the Specialist Nurse group felt that their post operative stay in hospital was about right compared with thirty-two (61.5%) of the women in the routine care group. Women in the Specialist Nurse group were significantly more satisfied with their time home from hospital as shown in Table 48.

Table 48 Time home from hospital				
	Specialist Nurse (Intervention) n = 50 (n, %)		Routine Care (Control) n = 52 (n, %)	
“About right time”	40	(80%)	32	(66%)
“Too soon”	6	(14%)	4	(8%)
“Not soon enough”	3	(6%)	16	(31%)
Total	50	(100)	52	(106)

X² = 10.6; df = 2; p = .005

Women were asked about peace at home whilst recovering from the surgery and 40 (94%) of women in the Specialist Nurse group and fifty (96%) women in the routine care group reported that it was more peaceful and quiet at home than in hospital, X² = .25; df = 1; p = .481.

5.14.6 Women visited at home by Specialist Nurse

Women in the Specialist Nurse group who were discharged home early from hospital were phoned the day after discharge and visited at home by the Specialist Nurse if required.

Forty-two (80%) of the women in the Specialist Nurse group were visited at home by the Specialist Nurse. Of these thirty six women (69%) had one visit, four (8%) had two visits and two each had three or four visits. Thirty eight women (76%) reported that they had found the visit at home by the Specialist Nurse worthwhile.

5.14.7 Consultation with the General Practitioner

Forty four (88%) women in the Specialist Nurse group and forty three (82%) in the Specialist Nurse group consulted their general practitioner following discharge

from hospital. There was no significant difference in the number of times women in both groups consulted their GP, $X^2 = 2.1$; $df = 2$; $p = .346$. The number of times women consulted with their GP is shown in Table 49.

Table 49 Number of times women consulted with their GP					
Number of times at GP	Specialist Nurse n = 44 (Intervention) (n, %)		Routine Care n = 43 (Control) (n, %)		Total (n, %)
Once	25	(57)	19	(44)	44
Twice	12	(27)	12	(28)	24
Three times or more	7	(16)	12	(28)	19
Total	44	(100)	43	(100)	87

5.14.8 Where women consulted with their General Practitioner

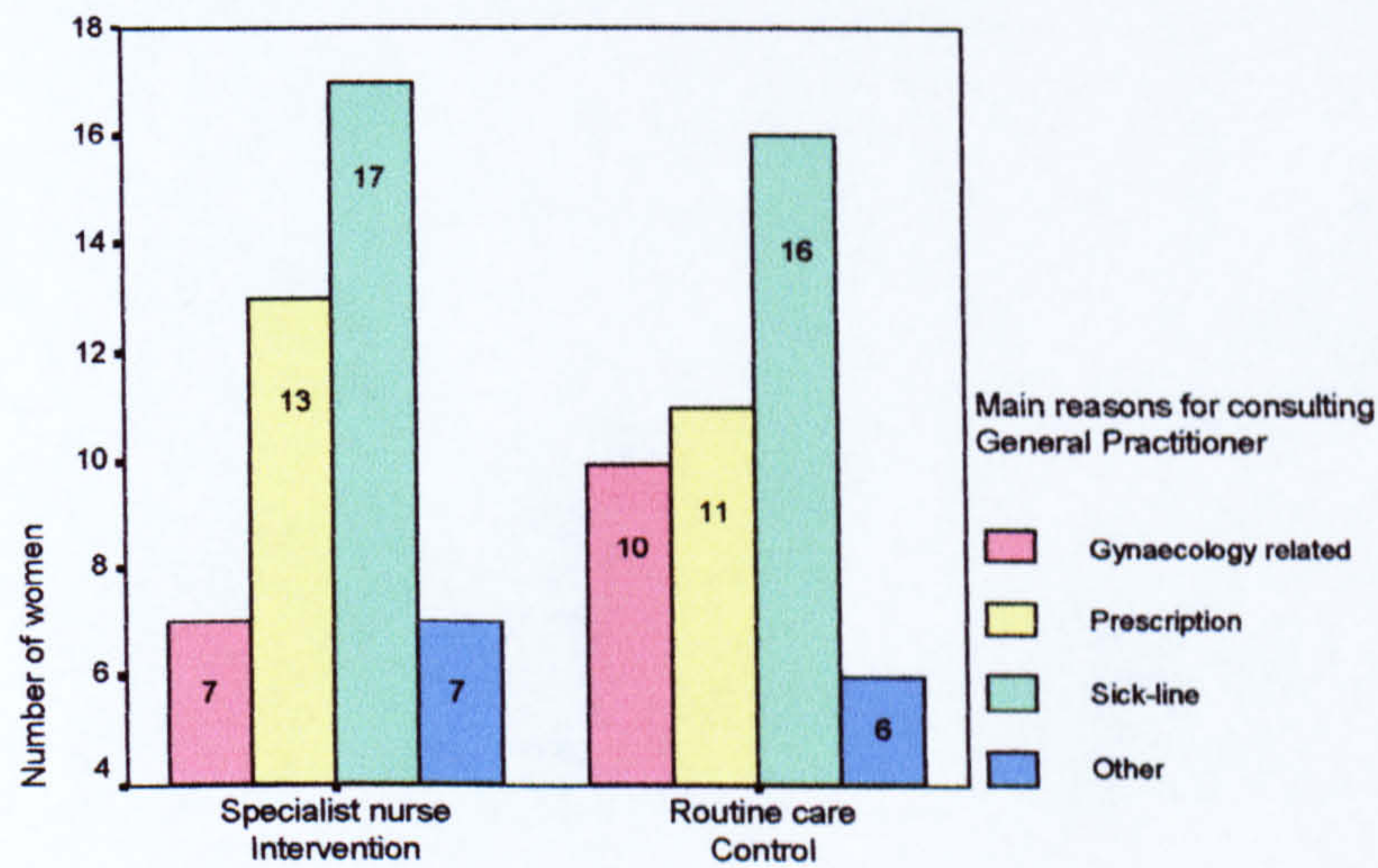
Two thirds of the women in each group consulted with their GP at the Doctor’s surgery. In addition eight (18%) women in the Specialist Nurse group and five (12%) women in routine care were visited at home, and two (4%) of women in each group were seen by the out of hours service. There was no significant difference in place of consultation in both groups, $X^2 = .74$; $df = 2$; $p = .691$. Table 50 shows where women consulted with GP’s. The women could have been seen in more than one place.

Table 50 Where women consulted with their GP					
Place of Consultation	Specialist Nurse n = 44 (Intervention) (n, %)		Routine Care n = 43 (Control) (n, %)		Total (n, %)
Doctors surgery	34	(78)	36	(84)	70
Home	8	(18)	5	(12)	13
Out of hours service	2	(4)	2	(4)	4
Total	44	(100)	43	(100)	87

5.14.9 Reasons why women consulted with their GP

Women were asked to identify the main reason for consulting with a GP. These were directly related to gynaecology condition, to obtain a prescription or sick line, and for other reasons. Figure 4 shows the main reasons why women consulted with their GP in both groups.

Figure 5. Main reasons for consulting with their GP



5.14.10 Type of treatment received from their GP

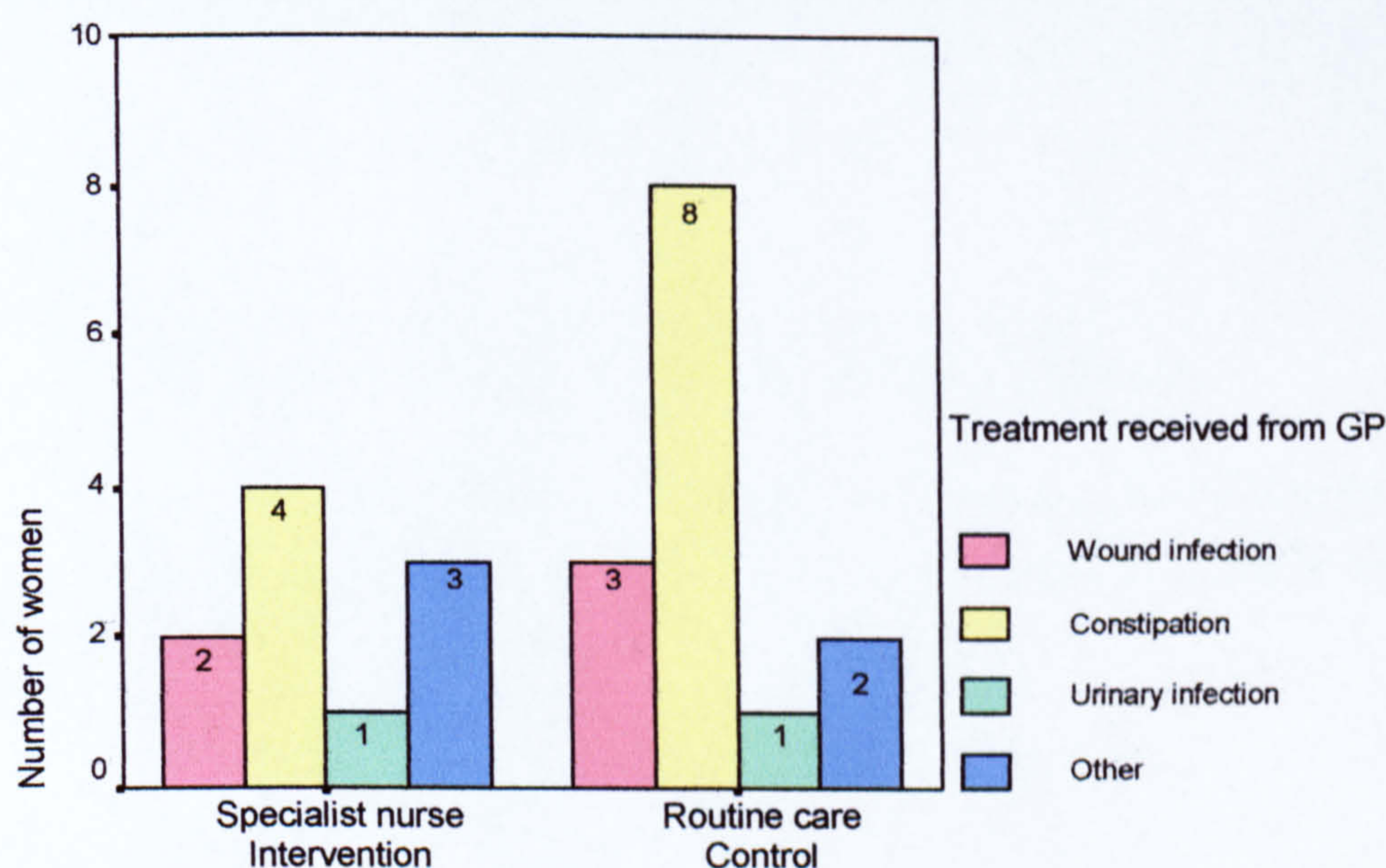
Ten women (20%) in the Specialist Nurse group reported receiving treatment from their GP. This compared with fourteen women (32%) in routine care. $X^2 = 1.8$; $df = 1$; $p = .180$. Women reported receiving treatment from their GP for wound infection, constipation, urinary infection and other reasons not related to gynaecology procedure (Table 51).

Table 51 Type of treatment women received from their GP

Type of treatment	Specialist Nurse (Intervention) n = 44 (n, %)		Routine Care (Control) n = 43 (n, %)	
Wound infection	2	(20)	3	(22)
Constipation	4	(40)	8	(57)
Urinary tract infection	1	(10)	1	(7)
Other	3	(30)	2	(14)
Total	10	(100)	14	(100)

There was no significant difference in the type of treatment received by women from their GP between both groups, $X^2 = 1.0$; $df = 3$; $p = .778$.

Figure 6. Type of Treatment from their General Practitioner



5.14.11 Return to normal after surgery

Fourteen women (28%) in the Specialist Nurse group and 18 (35%) in routine care said they felt back to normal within one to four weeks following surgery, 35 (70%) women in the Specialist Nurse group and 34 (65%) in routine care reported that they were not yet back to normal at the six week follow up appointment.

Over half the women in both groups reported that they were not yet back to normal at the six week follow up appointment although no other information was collected on the reasons for this. This may reflect an expectation of the recovery period being somewhere between six and twelve weeks subject to individual circumstances. Whilst it is recognised that individual recovery rates may be different, the women in both groups were given a general guide to recovery and told to expect to refrain from work for between six and twelve weeks.

5.14.12 Women told when to return to work

Thirty-six (35 %) women in the Specialist Nurse group and twenty-five women in routine care reported that they were told when to return to work. Table 52 shows the time women remembered being told that they could return to work.

Table 52 Women's recollections about what they were told about return to work.				
Parameter	Specialist Nurse (Intervention) n = 50 (n, %)		Routine Care (Control) n = 52 (n, %)	
1-4 weeks	2	(3)	2	(3)
5-8 weeks	19	(31)	14	(23)
9-12 weeks	14	(23)	9	(15)
Total	35	(56)	25	(40)

There was a significant difference in recollection of advice given to women on when to return to work, however both groups were told that they could return to work between six and twelve weeks, $\chi^2=7.2$; $df=2$; $p=.026$.

5.14.13 Time off from work

At the six -week follow up appointment women were asked how much time they planned to take off work. Seven (14%) women in both groups had returned to work within four weeks after surgery. Fifteen (30%) women in the Specialist Nurse group and 16 (31%) women in routine care indicated their planned return at eight weeks, 10 (20%) women in the Specialist Nurse group and 12 (23%) in routine care indicated that they would refrain from work for twelve weeks.

5.14.14 Amount and quality of information

Thirty-eight (76%) women in the Specialist Nurse group and thirty-four (65%) women in the routine care group reporting receipt of enough information on recovery and return to normal, $X^2 = 1.4$; $df = 1$; $p = .281$.

Women were asked to score (on a 0-10 scale) the amount and quality of information they were given on different aspects of their care including the surgical procedure and what to expect in hospital, their immediate recovery and when to resume normal activities, discharge from hospital and future health issues. The mean difference in scores is shown in Table 53.

Table 53 The amount and quality of information given to women				
Information	Specialist Nurse (Intervention) n = 50	Routine Care (Control) n = 52	Mean diff (Specialist Nurse - Routine Care)	Two sample t test
	Mean (SD)	Mean (SD)		
Surgical Procedure- What to expect in hospital	8.88 (2.68)	8.08 (2.24)	0.80	.684
Immediate Recovery – Resume normal activities	8.82 (2.34)	6.22 (3.46)	2.60	.013
Discharge from Hospital	8.92 (2.21)	7.87 (3.04)	1.05	.073
Health and Lifestyle Issues	6.53 (4.16)	3.13 (4.14)	3.40	.0001

The Two sample t test was used to test differences between the scores. The scores of the amount and quality of information on immediate recovery and future health issues were significantly higher in the Specialist Nurse group in comparison to routine care. This finding supports the provision of dedicated information by the Specialist Nurse. The significant improvement in the amount and quality of information on future health issues is a result of the planned intervention by the Specialist Nurse and this was not part of routine care.

5.14.15 Reported health behaviours of women at 6 week follow up

In the baseline assessment fourteen (27%) of the women in the Specialist Nurse group and thirteen (24%) of women the routine care group smoked cigarettes. In the follow up questionnaire seven (14%) women in the Specialist Nurse group and four (8%) women in the routine care group reported that they had altered their smoking habits since hospital admission. Two (4%) women in the Specialist Nurse group and one (2%) woman on the routine care group reported that they had stopped smoking at this time. In the follow up questionnaire thirty-seven (74%) women in the Specialist Nurse group and twenty-seven (52%) women in the routine care group reported that they carried out breast self- examination, $X^2 = 5.3$; $df = 1$; $p = .021$. Significantly more women in the Specialist Nurse group reported conducting breast self-examination compared with women in routine care. The reason for carrying out breast self- examination was reported by the women and is shown in Table 54.

Table 54 Reason for conducting breast self - examination				
Reason for Breast Self Exam	Specialist Nurse (Intervention) n = 50		Routine Care (Control) n = 52	
	(n, %)		(n, %)	
"Always done it"	29	(58)	25	(48)
Advised by Specialist Nurse	8	(16)	0	(0)
Other	0	(0)	2	(4)
No self breast exam	13	(26)	25	(48)
Total	50	(100)	52	(100)

$X^2 = 14$; $df = 3$; $P = .003$

Of the women in the Specialist Nurse group who reported breast-self examination; twenty-nine women (58%) stated that they "had always done so" and eight (16%) women did so because advised by the Specialist Nurse. Twenty-five (48%) women in routine care reported that they "had always done so", and two (4%) women reported that they carried out breast-self examination for another reason.

5.14.16 Information on health and lifestyle advice at 6 weeks follow-up

Table 55 shows receipt of information and advice on lifestyle issues and women who reported following lifestyle advice at 6 weeks follow up.

Table 55 Receipt of information and advice on lifestyle issues and if followed at 6 weeks follow up					
Advice given	Specialist Nurse (Intervention) n = 50 (n, %)		Routine Care (Control) n = 52 (n, %)		X ²
HRT	27	(54)	20	(38)	.043
Osteoporosis prevention	25	(50)	11	(21)	.009
Smoking	11	(22)	6	(11)	.001
Self breast exam	45	(90)	14	(27)	.001
Advice followed					
HRT	19	(38)	17	(33)	.302
Osteoporosis prevention	22	(44)	9	(17)	.004
Smoking	9	(18)	8	(15)	.874
Self breast exam	40	(80)	14	(27)	.001

There was significant difference in the number of women who said they followed advice on osteoporosis prevention ($p=.004$) and breast self- examination ($p= .001$) in the Specialist Nurse group compared to women in routine care. This may be due to the imbalance in the need for advice on osteoporosis prevention between both groups of women. The effect of the planned intervention and provision of health and lifestyle advice by the Specialist Nurse is shown.

5.14.17 Satisfaction with overall care experience at 6 weeks follow- up

Women were asked to report on their level of satisfaction with their overall care at the six-week follow-up appointment. Table 56 shows satisfaction rating of women in both groups at 6 weeks follow-up.

Table 56 Satisfaction with overall care reported by women at six weeks follow-up				
Satisfaction with overall care	Specialist Nurse (Intervention) n = 50		Routine Care (Control) n = 52	
	(n, %)		(n, %)	
Poor	0	(0)	1	(2)
Fair	3	(6)	4	(8)
Good	3	(6)	9	(17)
V Good	18	(36)	16	(31)
Excellent	26	(52)	22	(42)
Total	50	(100)	52	(100)

For Chi-square purposes, satisfaction was grouped into “poor/fair”, “good”, “very good” and “excellent”. There was no significant difference in satisfaction with overall care reported at six week follow up between both groups, $\chi^2=3.91$; df 3; $p=.271$.

5.15 Summary Results – At six week follow up

The summary results in this section are from the second questionnaire administered to women at their six-week follow up appointment. Symptoms experienced by women following discharge from hospital whilst at home were assessed and the outcome of hospital discharge was considered in terms of symptoms at home, complications, readmissions, treatment from the General Practitioner, satisfaction and costs of both types of care.

Summary of main findings

- The follow up symptoms scores show that pain remained the highest score, followed by constipation and disturbed sleep. There was no significant difference in symptoms experienced by women at home between the groups. There was a reduction, although not significant, in most of the symptoms reported at home compared to the symptoms experienced in hospital in both groups.
- There was improvement in the follow up paired mean scores in symptoms of pain, disturbed sleep and mobility in both groups. Improvement in disturbed sleep ($p=.016$) was significant in the Specialist Nurse Group. There was an increase in the symptoms of constipation, wind and anxiety in the Specialist Nurse Group. Disturbed sleep ($p=.002$) and pain ($p=.004$) were highly significant in the Control group in comparison with those in the Specialist Nurse Group.
- The provision of structured information on lifestyle issues was part of the Specialist Nurse intervention and there was significant difference in receipt of information and advice on lifestyle issues including; smoking ($p =.001$), breast self- examination, ($p =.001$).
- Significantly more women in the Specialist Nurse Group reported conducting breast self examination compared with women in Routine Care, ($p = .021$).

- The total length of post-operative hospital stay including additional days from hospital readmissions was significantly shorter in the Specialist Nurse group than in routine care, ($p=.001$). The mean post operative length of stay was 3.38 days SD (1.12) in the Specialist Nurse Group compared with a mean of 4.87 days SD (.91) in Routine Care.
- The majority of women in the Specialist Nurse Group were satisfied with their discharge time home from hospital with thirty eight (76%) women reporting that their post-operative length of stay in hospital was “about right” compared to the thirty-two (61%) women in Routine Care. Sixteen women (31%) in Routine Care thought their discharge home from hospital was not soon enough compared with three women (6%) in the Specialist Nurse Group $p = (.005)$.
- Satisfaction levels remained high with overall care at six weeks follow up and there was no significant difference in satisfaction in both groups of women regardless of their type of care.
- There was no evidence that sending women home early increased the workload of the GP. There was no significant difference in the number of women and the number of times women, in both groups consulted with their GP following discharge home from hospital regardless of their length of stay ($p=.346$).
- There was no difference in how much time women in both groups planned to refrain from work, although there was a significant difference in recollection of advice given to women on when to return to work between the groups ($p=.026$).

Chapter 6 – Results of Cost Consequence Analysis

6.1 Introduction

The economic evaluation set out to address the question, what is the expected cost per patient episode for women who receive early supported discharge from the gynaecology Specialist Nurse compared to women who receive routine care in gynaecology? The evaluation does not include costs from a patient or societal perspective and falls short of a full economic evaluation. A cost consequence analysis was conducted from the perspective of the NHS based on the costs from the gynaecology unit in the Western Infirmary Glasgow. All major items of resource use are reported as median or mean difference between the Specialist Nurse intervention group and routine care.

6.1.1 Major items of resource use

The major items of resource use in the Specialist Nurse and routine care groups are shown in Table 57. There was no significant difference in the length of operation in both groups and no significant differences were found in the requirement for additional surgery, blood transfusion, and readmission. No women in either group required admission to intensive care. The main difference between both groups as expected was found in the post-operative length of hospital stay.

Table 57 Major items of resource use Values given as n= mean (median)

	Specialist Nurse (Intervention) n= 52 Mean (Median)		Routine Care (Control) n= 54 Mean (Median)	
Length of operation (minutes)	56.54	(55.0)	58.98	(50.0)
Total length of hospital stay (days)	4.71	(4.0)	6.06	(6.0)
Women requiring additional surgery	2		4	
Readmissions	5		4	
Admission to Intensive Care Unit	0		0	
Blood transfusions	1		3	

6.1.2 Gynaecology inpatient costs

The costs of an inpatient day in gynaecology at the Western Infirmary Glasgow, taken from the Scottish Health Service Costs Book Manual 2003/04 are shown in Table 58. The direct medical costs, including theatre and the allocated costs, including hotel and hospital facilities costs combined, to give the gross cost of an inpatient day in gynaecology at the Western Infirmary Glasgow.

Table 58 Inpatient costs of gynaecology at the Western Infirmary Glasgow		Cost of an inpatient day in £
Medical including theatre costs	(Direct)	560
Allocated hospital hotel costs	(Allocated)	241
Total inpatient hospital cost per day	(Gross)	801

The gross cost of an inpatient day of £801.00 was obtained from the Scottish Health Service Costs Book Manual 2003/04.

6.1.3 Main Costs to NHS

The largest cost difference between the two groups is accounted for by the cost of the total length of hospital stay. Additional costs incurred by the Specialist Nurse group included the salary of the nurse taken at midpoint “G” grade and the travel costs incurred by visiting patients at home. Costs of blood transfusions and antibiotics were minor and similar in both groups. GP consultation costs were similar in both groups. Table 59 shows the main costs to the NHS of both groups.

Table 59 Main costs (in £) to NHS of Specialist Nurse supported discharge compared with Routine Care.				
	Specialist Nurse (Intervention) n = 52 Mean (median)	Routine Care (Control) n = 54 Mean (median)	Difference (Routine Care – Specialist Nurse)	Mann- Whitney P Value
Total Hospital length of stay cost	3789 (3203)	4850 (4805)	1061	.000
CNS cost	415 (415)	0.00 (0.0)	415	.000
Travel cost	3.94 (3.87)	0.00 (0.0)	3.94	.000
Blood transfusion cost	25.38 (0.00)	110.00 (0.00)	-84.62	.324
GP Consultation cost	15.26 (10.72)	17.27 (10.70)	-2.01	.582
Antibiotic cost	4.89 (3.35)	4.94 (1.97)	-0.05	.754
Total cost Western Infirmary	4253 (3644)	4982 (4825)	729	.000

The total mean cost of Routine Care was £729 more than the Specialist Nurse Group. The Specialist Nurse Group was associated with significantly lower total

costs to the NHS than Routine Care, resulting principally from the cost difference in the post-operative length of hospital stay.

6.1.4 Sensitivity analysis- changes in length of hospital stay

A sensitivity analysis was conducted to test the robustness of the results and the extent to which the results of the analysis would hold true in a range of alternative contexts. The RCT showed that the Specialist Nurse care resulted in earlier discharge from the gynaecology ward which was cost effective, offsetting the cost of the gynaecology Specialist Nurse. Data from the RCT suggested that the women in the routine care group tended to feel that they had been kept in hospital too long and this finding endorsed the need for the sensitivity analysis on changes in length of stay. The first part of the analysis was based on the assumption that the Specialist Nurse group may, in time, either increase or reduce the length of hospital stay by one day and routine care would reduce length of stay by one day.

6.1.5 Increase in Specialist Nurse care by one day

The sensitivity analysis was based on changes in the length of hospital stay and costs were calculated based on an increase of one day hospital stay in the specialist group. This assumption increased the mean total length of stay costs in the Specialist Nurse group from £3789 to £4574 and the total cost of care in this group from £4253 to £5039. If Specialist Nurse Group care was increased by one day, the total mean additional cost would be £57 more than Routine Care. This analysis is shown in Table 60.

Table 60 Sensitivity analysis of main costs (in £) to NHS of Specialist Nurse supported discharge increased by one day compared with Routine Care.						
	Specialist Nurse (Intervention) n = 52 Mean (Median)		Routine Care (Control) n = 54 Mean (Median)		Difference (Routine Care – Specialist Nurse)	Mann- Whitney P Value
Total length of stay cost	4574	(4004)	4850	(4805)	276	.000
Specialist Nurse cost	415	(0.00)	0.00	(0.00)	-415	.000
Travel cost	3.94	(0.00)	0.00	(0.00)	-3.93	.000
Blood transfusion cost	25.38	(0.00)	110.00	(0.00)	84.62	.324
GP consultation cost	15.26	(10.72)	17.27	(10.72)	2.01	.582
Antibiotic cost	4.89	(3.35)	4.94	(1.71)	0.05	.754
Total cost Western Infirmary	5039	(4444)	4982	(4825)	-57	.000

6.1.6 Specialist Nurse Group less one day

Further analysis of costs based on a reduction in the length of hospital stay by one day in the specialist group reduced the total length of stay costs in the Specialist Nurse Group from £3789 to £2988. Further reduction in the length of stay by one day in the Specialist Nurse group gave a total cost of £3452 compared with a total cost of £4982 for routine care. A reduction of Specialist Nurse Group care by one day could generate savings of £1530 over Routine Care. Figures are shown in Table 61.

Table 61 Sensitivity analysis of main costs (in £) to NHS of Specialist Nurse supported discharge reduced by one day compared with Routine care.						
	Specialist Nurse (Intervention) n = 52 Mean (Median)		Routine Care (Control) n = 54 Mean (Median)		Difference (Routine Care – Specialist Nurse)	Mann- Whitney P Value
Total length of stay cost	2988	(2403)	4850	(4805)	1862	.000
Specialist Nurse cost	415	(0.00)	0.00	(0.00)	-415	.000
Travel cost	3.94	(0.00)	0.00	(0.00)	-3.93	.000
Blood transfusion cost	25.38	(0.00)	110.00	(0.00)	84.62	.324
GP consultation cost	15.26	(10.72)	17.27	(10.72)	2.01	.582
Antibiotic cost	4.89	(3.35)	4.94	(1.71)	0.05	.754
Total cost Western Infirmery	3452	(2843)	4982	(4825)	1530	.000

6.1.7 Routine Care group less one day

Analysis of costs was based on a reduction in the length of stay by one day in routine care. One day less in routine care reduced the cost of the mean total length of stay in this group from £4854 to £4049. The total mean cost of Routine Care was £4181 compared with £4252 for Specialist Nurse Group care and supported discharge giving £72 additional cost over Routine Care. The costs are shown in Table 62.

Table 62 Sensitivity analysis of main costs (in £) to NHS of Routine Care reduced by one day compared with Specialist Nurse supported discharge.						
	Specialist Nurse (Intervention) n = 52 Mean (median)		Routine Care (Control) n = 54 Mean (median)		Difference (Routine Care – Specialist Nurse)	Mann- Whitney P Value
Total length of stay cost	3789	(3203)	4049	(4004)	260	.000
Specialist Nurse cost	415	(0.00)	0.00	(0.00)	-415	.000
Travel cost	3.94	(0.00)	0.00	(0.00)	-3.93	.000
Blood transfusion cost	25.38	(0.00)	110.00	(0.00)	84.62	.324
GP consultation cost	15.26	(10.72)	17.27	(10.72)	2.01	.582
Antibiotic cost	4.89	(3.35)	4.94	(1.71)	0.05	.754
Total cost Western Infirmary	4253	(3644)	4181	(4024)	-72	.055

6.1.8 Summary changes is length of hospital stay

These results show that Specialist Nurse supported discharge in gynaecology is cost effective. The reduction in the length of hospital stay and associated costs offset the cost of the gynaecology Specialist Nurse. A summary of the sensitivity analysis of changes in length of hospital stay is in Table 63.

Table 63 Sensitivity analysis changes in length of hospital stay main costs (in £) to NIIS.						
Assumption(mean cost difference)	Specialist Nurse (Intervention) n = 52 Mean (median)		Routine Care (Control) n = 54 Mean (median)		Difference (Routine Care – Specialist Nurse)	Mann- Whitney P Value
Total cost study groups at Western Infirmary	4253	(3644)	4982	(4825)	729	.000
Total cost of Specialist Nurse group increased by one day	5039	(4444)	4982	(4825)	-57	.051
Total cost of Specialist Nurse group reduced by one day	3452	(2843)	4981	(4824)	1530	.000
Total cost of Routine Care reduced by one day	4253	(3644)	4181	(4024)	-72	.055
Total cost of both groups reduced by one day	3452	(2843)	4181	(4024)	729	.000

6.1.9 Costs of an inpatient day in gynaecology

The range of costs for all Scottish hospitals with inpatient beds is presented in Table 64. This shows the average number of beds, average occupancy and costs per inpatient day. The application of sensitivity analysis to allow comparison of costs of Specialist Nurse intervention with routine care in all Scottish hospitals is also shown in Table 64.

The average number of staffed beds, average bed occupancy and total cost per day split by direct medical costs and allocated hotel facilities costs for all Scottish hospitals is shown in Table 64.

Three hospitals had very high costs per inpatient day including; Gilbert Bain, Lerwick with the highest cost of £2,554.00 followed by the Victoria in Kirkcaldy at £2,359.00, and the Victoria Infirmary, Glasgow with a cost of £2,114.91. These costs are substantively above the others and the reasons for such high costs are unclear. The next highest cost was Falkirk Royal Infirmary at £1,117.59 per inpatient day.

Two hospitals had very low costs; Uist and Barra at (£136.86) and Garrick in Stranraer at (£147.25) but both of these units had no dedicated beds. Units with no dedicated beds have costs that are difficult to determine and their relevance is questionable. Other low costs were found in the Royal Alexandria hospital (£433.92) and Crosshouse (£451.38) - these units had 17 and 24 gynaecology beds respectively. Small hospitals in very rural settings may have costs which are not comparable with hospitals within an urban setting due to factors separate from clinical cost.

The overall Scottish average weighted by the number of admissions in the “Blue Book” was £649.14 per inpatient day in gynaecology. The size of the gynaecology units varies enormously between hospitals and several (six) do not have dedicated gynaecology beds and presumably access beds from within the surgical division. Therefore the average occupancy figures are misleading when applied to such hospitals.

Table 64 All Scottish hospitals inpatient gynaecology staffed beds, average occupancy and costs per inpatient day from NHS Health Service Cost Book Manual 2003/04

Number of Hospitals: 32	Average staffed beds	Average occupancy	Direct Cost per IP Day	Allocated Cost per IP Day	Total Cost per IP Day
Gilbert Bain, Lerwick	0	100.0	£1,647.00	£907.00	£2,554.00
Victoria Kirkcaldy	0	100.0	£1,969.50	£389.50	£2,359.00
Victoria Infirmary, Glasgow	6	57.3	£1,534.31	£580.60	£2,114.91
Falkirk Royal Infirmary	4	54.9	£552.24	£565.35	£1,117.59
Wishaw General	8	58.4	£737.35	£249.42	£986.77
Ayrshire Central	0	100.0	£655.43	£224.50	£879.93
Perth Royal Infirmary	8	46.4	£575.44	£273.13	£848.56
Western / Gartnavel	12	44.4	£559.73	£241.12	£800.85
Borders General	12	44.2	£657.76	£140.18	£797.94
NRIE, Little France	25	64.2	£619.75	£174.90	£794.65
Inverclyde Royal Hospital	9	48.5	£634.02	£141.85	£775.86
Glasgow Royal Infirmary	15	47.3	£555.56	£193.42	£748.98
Ninewells	13	70.5	£466.78	£269.86	£736.65
Forth Park, Kirkcaldy	24	50.7	£504.56	£205.76	£710.32
Stirling Royal Infirmary	29	38.3	£554.21	£120.20	£674.41
Hairmyres, East Kilbride	10	68.2	£509.58	£160.36	£669.94
Monklands Hospital	9	90.1	£555.41	£109.59	£665.00
Southern General (SGH)	29	45.9	£487.20	£167.43	£654.64
Vale of Leven, Alexandria	4	100.0	£517.07	£95.04	£612.11
Western Isles, Stornoway	6	39.0	£394.82	£202.34	£597.16
Balfour, Kirkwall	0	95.7	£435.41	£146.09	£581.50
Stobhill, Glasgow	35	48.2	£409.04	£168.12	£577.17
D&G Royal Infirmary	13	72.3	£399.15	£149.01	£548.16
Raigmore, Inverness	17	62.9	£380.63	£160.96	£541.59
Aberdeen Royal Infirmary	48	72.5	£389.39	£146.64	£536.03
Caithness General - HAHT	6	33.1	£340.27	£172.38	£512.65
St. John's at Howden	10	68.3	£308.39	£144.57	£452.95
Crosshouse Hospital	24	69.4	£333.14	£118.24	£451.38
Dr. Gray's, Elgin	5	79.2	£283.40	£160.83	£444.23
Royal Alexandra Hospital	17	63.7	£349.56	£84.36	£433.92
Garrick, Stranraer	0	100.0	£124.57	£22.68	£147.25
Uist & Barra Hospital	0	100.0	£85.00	£51.86	£136.86
Totals or Averages (weighted)	399	58.1	£478.23	£170.91	£649.14

6.1.10 Sensitivity analysis - gynaecology wards in all Scottish hospitals

In addition to the assessment of costs and changes in length of stay a further sensitivity analysis was carried out to examine the potential effect of the extension of the Specialist Nurse Group model of care to gynaecology units across all Scottish hospitals. The same set of assumptions in the study cost analysis were applied and tested using the inpatient gynaecology day costs from the Scottish Health Service Costs Book Manual 2003/04 for all other Scottish hospitals.

The effect of the Specialist Nurse intervention was examined using individualised costs from all Scottish hospitals. As an example a comparison of the total mean costs of Specialist Nurse supported discharge and routine care in all the Glasgow hospitals is shown in Table 65. The costs of the Western Infirmary are comparable with Glasgow Royal Infirmary and higher than costs at both Stobhill and the Southern General hospitals. This also serves to highlight the apparently high costs of gynaecology inpatient stay in the Victoria Infirmary.

Table 65 Sensitivity analysis of total mean cost (in £) comparison of Specialist Nurse and Routine Care in Glasgow hospitals.					
Hospital run total	Specialist Nurse (Intervention) n = 52 Mean (median)	Routine Care (Control) n = 54 Mean (median)		Difference (Routine Care – Specialist Nurse)	Mann Whitney P Value
Western Infirmary	4253 (3643)	4982	(4825)	729	.000
Royal Infirmary	4233 (3627)	4957	(4800)	724	.000
Stobhill Hospital	3195 (2749)	3627	(3482)	432	.000
Southern General	3561 (3059)	4096	(3947)	535	.000
Victoria Infirmary	10470 (8900)	12939	(12709)	2469	.000

Within Glasgow the costs vary from (£2, 114 .91) for the Victoria Infirmary to (£577.17) at Stobhill General Hospital.

The full results for all the inner city comparable gynaecology units show significant cost reduction apart from those hospitals with apparently much lower costs than the others. Table 66 shows the total mean costs of both models of care applied to all Scottish hospitals from the most expensive to least expensive.

Table 66 Sensitivity analysis total mean cost (in £) comparison of Specialist Nurse and Routine Care, scenario in all other Scottish Hospitals

Hospital run total	Specialist Nurse (Intervention) n = 52 Mean (median)		Routine Care (Control) n = 54 Mean (median)		Mann Whitney P Value
Gilbert Bain, Lerwick	12547	(10656)	15598	(15344)	.000
Victoria Kirkcaldy	11624	(9876)	14417	(14173)	.000
Victoria Infirmary, Glasgow	10470	(8900)	12939	(12709)	.000
Falkirk Royal Infirmary	5752	(4910)	6800	(6725)	.000
Ayrshire Central	4627	(3960)	5461	(5299)	.000
Perth Royal Infirmary	4479	(3834)	5271	(5111)	.000
Western Infirmary	4253	(3643)	4982	(4825)	.000
Borders General	4239	(3632)	4964	(4807)	.000
Glasgow Royal Infirmary	4233	(3627)	4957	(4800)	.000
NRIE, Little France	4224	(3619)	4944	(4787)	.000
Inverclyde Royal Hospital	4135	(3544)	4831	(4675)	.000
Ninewells	3949	(3387)	4593	(4439)	.000
Stirling Royal Infirmary	3655	(3138)	4216	(4066)	.000
Hairmyres, East Kilbride	3634	(3120)	4189	(4039)	.000
Monklands Hospital	3610	(3100)	4159	(4010)	.000
Southern General	3561	(3059)	4096	(3947)	.000
Vale of Leven	3360	(2889)	3839	(3692)	.000
Western Isles, Stornoway	3289	(2828)	3748	(3602)	.000
Stobhill, Glasgow	3195	(2749)	3627	(3482)	.000
Dumfries and Galloway	3058	(2633)	3452	(3308)	.000
Raigmore, Inverness	3027	(2606)	3419	(3269)	.000
Aberdeen Royal Infirmary	3000	(2584)	3378	(3235)	.000
Caithness General	2890	(2491)	3237	(3095)	.000
St John's at Howden	2607	(2252)	2875	(2737)	.042
Crosshouse Hospital	2600	(2456)	2866	(2728)	.000
Dr. Gray's Elgin	2566	(2217)	2827	(2685)	.000
Royal Alexandria Hospital	2517	(2176)	2760	(2623)	.000
Wishaw General	5133	(4387)	6108	(5940)	.000
Balfour, Kirkwall	3215	(2766)	3654	(3509)	.000
Garrick, Stranraer	1161	(1029)	1024	(903)	.000
Forth Park, Kirkcaldy	3825	(1159)	4434	(4281)	.000
Uist & Barra	1112	(988)	961	(841)	.000
Scottish average (weighted)	3535	(3037)	4063	(3914)	.000

6.2 Summary Results - Cost Consequence Analysis

- The total mean cost of Routine Care was £729 more than Specialist Nurse Group care. The Specialist Nurse Group was associated with significantly lower total costs to the NHS ($p=.0001$) than Routine Care, resulting principally from the cost difference in the post operative length of hospital stay.
- Within the Western Infirmary Glasgow, the site of this study, Specialist Nurse interventions led to cost savings of £729 per patient in a unit which had total costs per inpatient day of £800.85. This is an illustration of the scale of potential savings which could be anticipated if this model of care was applied to other hospitals.
- A reduction of Specialist Nurse Groups care by one day could generate savings of £1530 over Routine Care. But reduction of Routine Care by one day would give almost equivalent costs with Specialist Nurse care costing £72 more.
- The sensitivity analysis showed difficulties comparing small units and or rural units with larger urban units, although comparing the model with the Scottish average cost of an inpatient day showed significant reduction in costs ($p=.001$). The Specialist Nurse intervention applied to Scottish hospitals would provide significant cost reduction in all hospitals apart from those with the lowest costs.

6.3 Summary of Main Findings of the RCT

The SF-36 health survey questionnaire was used to assess the self-reported health status of women in both groups prior to surgery and at six weeks follow up. Women were also assessed on receipt of information on return to normal activities and lifestyle issues. A cost consequence analysis was conducted to compare the costs of both models of care. The main findings from the RCT and economic evaluation are summarised.

- There was no significant difference in the health status and SF-36 scores of both groups regardless of earlier hospital discharge. However, there was improvement in the follow up paired mean scores in six of the eight SF-36 dimensions namely physical functioning, bodily pain, role emotional, mental health, energy/vitality and general health perception, the same in both groups.
- The total length of post-operative hospital stay including additional days from hospital readmissions was significantly shorter in the Specialist Nurse group than in routine care. Planned reduction in the length of post-operative hospital stay was part of the Specialist Nurse intervention. The mean number of days in hospital care following surgery was 3.38 SD (1.12) in the Specialist Nurse Group and 4.87 SD (.91) in Routine Care.
- There was no significant difference in complications ($p=0.871$) or readmission to hospital ($p=0.683$) in both groups of women although the sample was not adequately powered to detect a significant difference of these rare events between both groups.
- There was no evidence that sending women home early increased the workload of the general practitioner. There was no significant difference in the number of times women consulted with their GP between the groups.
- There were significant differences in receipt of information by women in the Specialist Nurse group on when to resume normal activities including; housework ($p=.045$), driving ($p=.0001$), sexual intercourse ($p=.001$),

exercise ($p=.000$), and when to return to work ($p=.026$). This suggests that women in the Specialist Nurse group received more routine information on return to normal activities following surgery than women in routine care.

- There was a significant difference in receipt of information in lifestyle advice by women in the Specialist Nurse Group in comparison to Routine Care, ($p= .001$). This demonstrates the planned effect of the Specialist Nurse in the provision of lifestyle information which was not always part of Routine Care.
- There was no significant difference in satisfaction of women at hospital discharge and at six weeks follow up. Levels of satisfaction were similar in both groups of women and satisfaction remained high regardless of the type of care.
- Specialist Nurse led early supported discharge was associated with significantly lower total costs to the NHS ($p=.0001$) than Routine Care in gynaecology.

Chapter 7 – Discussion

7.1 Introduction

This thesis had two general aims. These were to evaluate the effectiveness and cost of a new model of early supported discharge, led by a Specialist Nurse in the gynaecology unit at the Western Infirmary in Glasgow. This chapter discusses the findings from the randomised trial and economic evaluation of Specialist Nurse led early hospital discharge compared with routine care gynaecology.

The research questions which were previously identified in Chapter 1 were set to address; the effectiveness of the new model of care for patients, and to examine differences and costs of Specialist Nurse care, compared with conventional services and routine care in gynaecology. In order to answer the research questions, a range of research methodologies were utilised as reported previously in the methods chapter. The methodology used was a Randomised Controlled Trial and the Economic Evaluation included a cost consequence analysis which was conducted as a sub study of the controlled trial. The limitations of the methodologies used in each of the studies are outlined.

The primary outcome measure was the assessment of women's health status before and after major gynaecological surgery. The study hypothesised that women receiving Specialist Nurse care and earlier hospital discharge following major abdominal surgery for benign gynaecological conditions, would have significantly higher health status scores as measured by the SF-36 questionnaire compared to women receiving routine care. The SF-36 health related quality of life questionnaire was specifically used to assess physical functioning scores in women following hysterectomy and enable examination of any differences in recovery of women receiving different types of care. Assessment was made four weeks prior to surgery and at six weeks follow up (giving sufficient time to recover from the surgery and get back to normal life). This enabled comparison and discussion of women's health status, including SF-36 baseline scores and changes in paired data at six weeks follow up.

Assessment of complications, readmission, length of hospital stay, post operative symptom scores, receipt of information on return to normal activities, lifestyle advice, satisfaction and cost of care was carried out. Further questionnaires were compiled and administered to collect the additional information required to allow the research questions to be answered. The second part of the discussion addresses the findings from the two further questionnaires that were designed to assess the women's immediate post-operative recovery, hospital care and convalescence at home 6 weeks later. The final section discusses the cost of both processes of care and the findings from the cost consequence analysis.

7.1.1 Overview of significant findings of the RCT

There are few controlled studies and economic evaluation of changes in models of health care within the gynaecology setting. To my knowledge, this study was the first RCT to examine the effect of "Early Hospital Discharge" following major gynaecological abdominal and/or pelvic surgery with the provision of support from a Specialist Nurse.

The patient questionnaires achieved high response rates at all stages of the study. The mean age of women was 47 years in the Specialist Nurse group and 46 years in the routine care group. The age range was 17-83 years. The baseline characteristics of women randomly allocated to both groups were very similar and there was no evidence of selection bias in that there were no significant differences in demographics, employment characteristics and baseline health status between both groups.

All of the women in the study underwent major abdominal or pelvic surgery for benign gynaecological disease. Overall, the surgical procedures in both groups were not different but, there was a substantial difference in the number of women losing both ovaries with a bilateral salpingo-oophorectomy being performed in 39% of the Specialist Nurse Group compared with 22% in the Routine Care Group. This is important as it will have a substantial impact on post operative symptoms and lead to the need to address the issue of osteoporosis.

There was no difference found in the length of the surgical procedures between the groups of women. Complication rates were similar in both groups of women and the majority of the complications occurred following abdominal hysterectomy in both groups of women with 17% in the Specialist Nurse group and 19% in routine care. Complications included blood loss (requiring blood transfusion), bladder perforation, bowel damage, wound dehiscence, wound infection, vault haematoma, retention of urine and urinary tract infection. The number of women who were readmitted to hospital with complications was small and not significant in either group.

7.1.2 Women's subjective health status

The importance of subjective accounts of health in monitoring outcomes and assessing the effect of new methods and systems of care, has been acknowledged. It is now recognised that the traditional measures of morbidity and mortality do not always capture the potential benefits of health care interventions particularly those that can influence a wide number of variables such as physical mobility, social life, emotional and overall well-being. The SF-36 health survey questionnaire has been shown to be internally consistent and valid.⁽⁹⁴⁾ The instrument attempts to capture a broad range of aspects of quality of life that are important to patients. The SF-36 health survey questionnaire was specifically used to assess physical functioning scores in women following hysterectomy and enable examination of any differences in recovery of women receiving different types of care.

The baseline SF-36 scores of both groups of women in the study were lower than normative values in women of equivalent age in the UK.⁽¹²⁸⁾ The scores were however comparable with other published baseline scores of women undergoing both medical and surgical management of menorrhagia.⁽¹⁴³⁾ Important changes in health status of women were identified following gynaecological surgery in both groups of women. The follow up paired mean SF- 36 scores were improved in six of the eight dimensions; including physical functioning, pain, emotional and mental health, energy/vitality and general health perception, the same in both groups. In both groups the physical functioning improvement was small and the

social functioning scores were slightly worse, which may reflect that women had undergone major gynaecological surgery and were naturally restricted during postoperative recovery and convalescence. The SF-36 questionnaire specifically asks about symptoms in the past four weeks and this instrument was chosen to reflect the initial post operative period and detect any changes resulting from early hospital discharge. There was no significant deterioration in physical functioning within the initial post operative period in both groups. Post-operative health status was similar in women undergoing earlier hospital discharge and those receiving routine care and standard discharge at six weeks follow up. There was improvement significant improvement in general health perception six weeks after surgery in both groups.

Previous studies have reported improvement in women's SF-36 scores following both medical and surgical treatment of benign gynaecological disease. Studies comparing treatment for menorrhagia have shown women receiving medical (drug) treatment alone did not indicate any substantial change in SF-36 scores, but patients receiving surgical treatment showed moderate to large changes in six of the eight health domains.⁽¹⁴²⁾ Improvement in SF-36 scores have shown the benefits of surgical intervention TCRE and Hysterectomy over medical therapies.⁽²¹²⁾ This study has also shown significant improvements in health status following major gynaecological surgery in both groups of women. Direct comparison of the post SF-36 mean scores using the pre SF-36 mean score as a covariate showed no significant difference in each of the scores in both groups. Subjective improvements in health status have also been shown following a variety of interventions, including comparisons between nurse and doctor led services in primary care settings.⁽⁹⁸⁾⁽⁹⁹⁾ Improvement in women's health status was similar in both groups and this was regardless of the length of their hospital stay and type of care received in this study .

7.1.3 Reduction in the length of hospital stay

Reduction in the length of hospital stay was part of the planned Specialist Nurse intervention. The women in the Specialist Nurse group had significantly shorter length of hospital stay than those in routine care. The mean post operative length

of hospital stay in the Specialist Nurse group was 3.38 days compared with a mean of 4.87 days for women in routine care who were undergoing standard discharge practice. Women undergoing both types of care showed no significant difference in their reported symptoms at hospital discharge and at 6 weeks post operatively. This was regardless of the length of their hospital stay and women who went home earlier from hospital did not report any adverse effects.

Traditionally the standard length of stay following major gynaecological surgery was usually 10 days or more. ⁽²¹³⁾ This has changed over the past decade and it has been shown that post-operative length of stay in gynaecology is procedure specific, with reports of 2 days following vaginal hysterectomy and 3 days following laparoscopic procedures. Although uncertainty has remained about the safety and acceptability of earlier hospital discharge for women undergoing abdominal hysterectomy and recent controlled trials have shown the length of stay following abdominal surgery has remained static at 5 days. More recently, a small descriptive study of 32 women with planned lengths of stay of 2 days following abdominal hysterectomy and 1 day after laparoscopic assisted vaginal hysterectomy (LAVH) in a fast track setting demonstrated that it is possible to reduce the length of stay following abdominal hysterectomy. ⁽¹⁵¹⁾ The small observational study designed by Moller in a specific fast track setting has some similarities to the study within this thesis. However, limitations in the study design by Moller and her colleagues suggest that their findings should be interpreted cautiously. The main similarity with this work and the study in this thesis was the planned early discharge on the second post- operative day following major abdominal surgery.

Previous randomised trials of early hospital discharge have been restricted to patients undergoing relatively minor conditions such as hernia and varicose vein surgery. ⁽³³⁾ No randomised controlled trials have examined the effects of early hospital discharge following major gynaecological surgery. Uncertainty about shorter hospital stay following major surgical procedures has been evident and can be seen in an earlier prospective cohort study of women who were discharged home from hospital earlier, following abdominal hysterectomy. ⁽³⁶⁾ This study gave strong support to the notion that women could be safely discharged earlier

on post operative day 5 without any detrimental effect to their health or need for post discharge care. However, the authors suggested that all of the women who could safely tolerate a short stay were already being discharged early. The post operative length of stay in the study by Clark considered early discharge on the fifth post operative day as safe and appropriate for patients. This contrasts with the shorter post-operative discharge on day two that was achieved in the study presented in this thesis. This serves to highlight how perceptions about earlier hospital discharge have changed in the past 5 years with earlier post operative stays following major abdominal surgery in gynaecology now being considered.

The model of care led by the gynaecology Specialist Nurse was designed to support early hospital discharge and promote the concept of patient self-care and convalescence at home where appropriate. The model of care for women in the Specialist Nurse Group was based on the provision of structured information and advice on return to normal activities following surgery and planned early hospital discharge on the second post-operative day. The women in the Routine Care Group received the same information and advice on return to normal activities. They were encouraged to convalesce in hospital post-operatively and given standard discharge on operative day five or six. Women in the intervention group were encouraged to recover and convalesce independently at home with access to advice from a nurse with specialist knowledge in gynaecology if required. Women in the shorter stay group were contacted by telephone by the Specialist Nurse the day after discharge and then visited at home as deemed appropriate. This concept of the model supports an overall reduction in the length of acute hospital care and the total episode of care where possible following major gynaecological surgery. The results of the study demonstrated that the model of earlier hospital discharge, supported by a Specialist Nurse was safe and acceptable and showed no adverse effects on women's health status.

7.1.4 Transfer of care to General Practitioner's in the community

The study showed no difference in the number of times women consulted with their general practitioner and in the type of treatment women received in both groups of women following hospital discharge although it is recognised that this information was based on data from the patient perspective and did not include

data from GP's. Return to normal activities following surgery was also similar in both groups of women, the readmission rate was low, and recovery was uneventful. The study did not detect any significant differences in how much time women planned to take off work with the majority of women refraining from between six and twelve weeks reflecting the advice given to women in both groups. There was no evidence that sending women home earlier increased the workload of the general practitioner, which supports findings from two previous studies. ^(36, 37,38) However this evidence conflicts with studies and models of Early Hospital Discharge and Hospital at Home care, which have transferred patients care to the community and been shown to increase the overall episode and costs of care. One study of earlier hospital discharge, three days after abdominal hysterectomy, increased the GP's work and showed 36 home consultations were required in the early discharge group compared with 13 in standard discharge ($p=0.05$).⁽¹⁵⁴⁾ This policy of early discharge raised genuine concern about the transfer of hospital care to the community without the transfer of resource and influenced the subsequent development of early discharge schemes in gynaecology, which were then specifically designed to provide significant amounts of home follow up support for women, in order to avoid the transfer of care from hospital to community. One scheme for women following abdominal hysterectomy was supported by community liaison nurses and involved a number of follow up visits until 14 days following discharge. The methodology and findings were not well defined or described and little detail was given of the role of the community liaison nurse in this study. ⁽³¹⁾

The potential of transferring the burden of patient care from hospital to community was recognised prior to the implementation of the new model of early discharge, supported by the Specialist Nurse. In light of this, attention was paid to the process and the model of care introduced by the gynaecology Specialist Nurse in the study. The requirement for medical care during the post-operative recovery period was examined. Detailed discussions between the Consultant Gynaecologists, Specialist Nurse and local General Practitioners took place. This resulted in agreement and production of an integrated care pathway for patients based on the approach of early hospital discharge with self-care and convalescence at home where possible. This process ensured a comprehensive

understanding of the role of the Specialist Nurse and the proposed new model of care, and helped achieve a seamless process of care between hospital and home with clear communication between hospital and primary care staff.

7.1.5 Patient Information and Lifestyle advice

This model of early discharge and concept of self care for women following major gynaecological surgery reported in this thesis is supported by information and advice from a Specialist Nurse. There was significant improvement in receipt of information by women in the Specialist Nurse group, compared with those in routine care. Significant differences were shown about the timing of resumption of normal activities following surgery. Differences were shown in receipt of information on housework, sexual intercourse, and when to return to work, compared to those receiving routine care. These positive findings show that the Specialist Nurse was more effective in the provision of routine information on return to normal activities following surgery, than the nurses in routine care. This may be explained in part because the Specialist Nurse provided dedicated information advice and support to women as part of her role whereas the ward nurses only gave women information as part of the standard process of care in a busy ward environment.

The importance of preparing patients adequately for their surgery and post-operative recovery has also been recognised. The provision of patient information is an important part of the care process for women in gynaecology, and this is particularly so when shorter lengths of hospital stay make less time for patient contact with staff and information giving.^{(113) (114)} Specific information requirements of women under-going hysterectomy have been reported and include information on return to normal household activities such as driving, housework, lifting, sexual activity, sport, and work. This type of information has been routinely given to women following gynaecological surgery in a number of gynaecology units in the UK and was given to all women in this study regardless of their type of care. Earlier hospital discharge from acute hospital settings has highlighted the need to provide more detailed information to patients and carers to

enable them to effectively manage care at home. It has been suggested that providing written health information can assist in this self-management. ⁽²¹⁴⁾

In addition to routine information and advice given to women in both groups of the study another part of the planned Specialist Nurse intervention was in the provision of specific lifestyle advice on smoking cessation, healthy diet, alcohol consumption, regular exercise and breast self-examination. These issues all tie in with government public health initiatives aimed at encouraging greater responsibility and healthier lifestyle choices designed to support disease prevention.

In the current study the Specialist Nurse had a “hands on” role in clinical assessment and management of women following gynaecological surgery. Women in the early discharge group reported receipt of health and lifestyle information and advice. This was in addition to the routine information and advice given to women about postoperative recovery and return to normal activities following surgery. The women received dedicated lifestyle information and advice on HRT, osteoporosis prevention, healthy diet, alcohol consumption, smoking cessation, and breast self-examination. This information was given specifically to women as part of the Specialist Nurse intervention and was not routinely given in standard care although some women in routine care may have received lifestyle advice if directly relevant to their individual care. The study showed a significant difference in receipt of lifestyle advice and information to women in the Specialist Nurse group in comparison with women in routine care. The significant findings relating to information on HRT and osteoporosis prevention can not be interpreted because of the difference in the number of women undergoing bilateral salpingo-oophorectomy between the groups. Removal of both ovaries has a substantial impact on the post operative symptoms of women and the need for advice on HRT and osteoporosis.

Previous randomised studies have recognised the contribution and role of the nurse in the follow up care of patients although the effect of the nurse was not evaluated in either of these studies.⁽³³⁾⁽³⁵⁾ The key role components of the Specialist Nurse in this study were the autonomous clinical management of

patients and the provision of individual information and lifestyle advice. The study shows that the Specialist Nurse can successfully impart such advice with improved patient satisfaction and intention to act on this information at six weeks follow up.

7.1.6 Patient Satisfaction

It is known that patient satisfaction is multi-dimensional concept and difficult to measure.⁽⁸¹⁾ In the current study the rates of satisfaction were high in both groups and women were satisfied with their hospital experience and overall episode care regardless of the length of hospital stay. However, women in the Specialist Nurse group reported significantly more satisfaction with their length of hospital stay than women in routine care. The majority (80%) of women in the Specialist Nurse group thought their post-operative length of stay in hospital was “about right” compared with (61%) of women in the routine care group. Some studies have shown that a shorter length of stay is associated with lower patient satisfaction⁽³³⁾⁽¹⁵⁴⁾ although other studies have shown the opposite.⁽³²⁾⁽¹⁵¹⁾

One of the studies reporting lower patient satisfaction was an earlier study of early discharge following hernia and inguinal hernia. This is one of the few randomised studies reporting changes in length of hospital stay.⁽³³⁾ This study was conducted prior to the general introduction of day surgery and acceptance of shorter hospitalisation for patients following minor procedures in the UK. The reports of lower patient satisfaction in this study may reflect the attitudes towards changes in hospital length of stay at this time. The satisfaction results may reflect this. The recent study by Moller and her colleagues of early discharge in a fast track setting suggests that patients who are adequately prepared for surgery are satisfied with shorter hospital stay.⁽¹⁵¹⁾ This is in contrast to the earlier findings of Adler,⁽³³⁾ and may reflect current changes in health service provision and patients’ expectations of care. The satisfaction results in the study the thesis show that women are highly and equally satisfied with their care regardless of their length of hospital stay. This is consistent with findings of other recent gynaecological studies showing high levels of satisfaction with gynaecological treatment. The only controlled trial of early hospital discharge following hysterectomy was evaluated as part of a large evaluation of “Hospital at Home” care. This study did not detect any

differences in satisfaction with service for patients recovering from hysterectomy.
(37)

It is now recognised that greater levels of satisfaction do not necessarily lead to improved health outcome, although patient preference and the weight of public opinion is evident in respect of health service changes. A study of systematic methods for identifying alternatives to hospital admission recognised that patients should have a much greater voice in the way care is delivered. This work suggested that a combination of patients, carers and clinical professionals should decide on the best alternatives to hospital care.⁽¹⁵²⁾

Government policies in support of patient choice and partnerships for care are expected to lead to improvements in knowledge, communication and organisation of care.⁽²¹⁵⁾ Perceptions about hospital care and patient and public expectations of health care in general have changed dramatically, partly because information on health care is more readily available and knowledge is greater, but also as a direct result of the media and public campaigning for better health and health services. Differences in levels of patient satisfaction with discussions about care have been shown in evaluation of “Hospital at Home” compared to acute hospital care.⁽¹⁵²⁾

7.1.7 Summary of earlier hospital discharge model of care

Women undergoing major abdominal and pelvic surgery were discharged home earlier with provision of support from a specialist gynaecology nurse. The results of the study show that the duration of hospital stay can be shortened by the introduction of a Specialist Nurse without introducing any adverse physical and psychological effects to women. The concept of the model supports patient self-care and an overall reduction in the length of acute hospital care and the total episode of care following major gynaecological surgery. Earlier hospital discharge on the second post-operative day is an acceptable alternative to current routine practice in gynaecology.

7.2 Limitations of the Randomised Controlled Trial

In any study it is important to consider potential limitations in terms of patient selection, methodology, interpretation of results and the conclusions that have been reached. The limitations of the RCT and comparison of the new model of Specialist Nurse care with routine care in gynaecology are discussed in this section.

Current practice supports using random allocation in clinical trials and ensuring that randomisation schedule is adequately concealed. Non-randomised trials and randomised trials with inadequately concealed allocation, can result in over estimates of effect, which can reverse or mask the direction of effect. ⁽²¹⁶⁾⁽²¹⁷⁾ Making a decision on the basis of small clinical trials, even when they are properly randomised, requires some caution because of chance effects and the risk of biased reporting.

It has been recognised that when an intervention involves changing the organisation of health care in a unit or department, all patients attending the unit will be affected. Similarly an intervention targeted at changing practice and behaviour of health professionals can lead to modification of behaviours, once they have been exposed to the intervention. In such a situation it can be difficult or impossible for staff to revert to previous practice when treating control patients. Randomisation of patients in these situations runs the risk that control patients would be influenced by the experimental intervention. In addition it is also possible that experimental patients may affect the behaviour of the controls by sharing information acquired in a patient education programme. Robertson and Sibbald ⁽²¹⁶⁾ reported that one way of dealing with this is to use group randomisation. However this has disadvantages in sample size requirements as the number of patients required would have been beyond the scope of this study.

A weakness of the study was the relatively small sample size. The intended sample size was not achieved because of slow recruitment and practical issues encountered in the delivery of the service. The sample size used in the study was based on a publication by Ruta et al, who calculated sample sizes from a population study for each of the eight individual domains of the SF-36 to provide sufficient power to reach significance.⁽¹⁹⁸⁾ The sample sizes were; physical

functioning 26, social functioning 25, in role limitations, role physical 64, role emotional 62, mental health 14, pain 26, energy and fatigue 18, and general health 19. To detect a difference of 20 points in changes over time for all eight SF-36 variables a sample of 64 is required in each group. The study did not reach the required sample size of 128 (64 women in each randomly selected group that Ruta suggests). However the study did provide sufficient power to estimate effects from 6 of the SF-36 health domains. Studies using the SF-36 do not always assess all eight SF-36 domains, primarily to avoid multiple statistical testing, but also because the eight domains may have different relevance to the subjects and condition under study. The key SF-36 measure of relevance in this study, examining the impact of early hospital discharge following major abdominal surgery was physical functioning and a sample size estimate of only 26 patients was required to show a 20 point difference in the score for this health domain.

7.2.1 Contamination

As the study progressed it became apparent that patients, nurses and doctors accepted the new model of early discharge. Patients in routine care began to request earlier hospital discharge forty-eight hours after their surgery. All of the consultant gynaecologists were happy to discharge women earlier. This became evident as several consultants agreed to let women go home early on request. A small number of women in routine care including non-study patients were discharged home earlier without provision of additional support from the gynaecology Specialist Nurse and unfortunately this led to some difficulties; as patients being discharged home earlier, without preparation, led to potential contamination of the control group. This situation was compounded because recruitment to the study had slowed down considerably due to cancellation of the elective programme in favour of other priority work in the Trust, and the study was stopped at 111 patients short of reaching the proposed sample size of 128 patients. Contamination of control participants has two related effects, it reduces the point estimate of an interventions effectiveness which may lead to a type II error and rejects an effective intervention as ineffective because the observed effect size was neither statistically or clinically significant. The threat of contamination is an issue in some controlled trials and cluster trials have been

used to prevent contamination. Cluster trials are usually much larger than individual randomised trials and can be susceptible to recruitment bias.⁽²¹⁸⁾

7.2.2 Observer influences and bias

The CONSORT statement (consolidated standards of reporting trials) was produced to help authors improve on the reporting of Randomised Controlled Trials.⁽²⁰¹⁾ The revised check list includes 22 items, selected because empirical studies indicate that not reporting this information is associated with biased estimates of treatment effect, or because the information is essential to judge the reliability or relevance of the findings. The CONSORT statement was used to report the trial process and ensure transparency.

The collection of the data set in this study necessitated close clinical contact between the researcher and the women in the study and it could be argued that this could influence the outcome. The questionnaires were self-completed by the women when they attended the clinic and the assessor was careful to avoid influencing the patients in terms of their responses.

7.2.3 Multiple statistical hypotheses testing

The p-values were set for a significance level of 0.05 and were not adjusted to take account for errors arising through the process of multiple comparisons. However, the main parameters that were shown to be highly significant with p-values of 0.001 or less and therefore it is less likely that the problem of multiple comparisons will change the interpretation of these results.

7.2.4 Generalisability of the results

Generalisability is the extent to which the results of a study undertaken in a sample of a population can be applied to the population as a whole.⁽²¹⁹⁾ In order to address this issue, it is necessary to be able to demonstrate that the characteristics of the sample studied are representative of the population from which they were selected. It is recognised that a number of variables that are not explicitly provided can influence the outcome of the procedure. The sample was typical of other study samples in the gynaecology setting and the findings of this study were generalisable to other women with similar group characteristics undergoing major

surgery for benign gynaecological conditions. Therefore the results may be used as supporting evidence within gynaecology and other surgical clinical areas.

To comprehend the results of an RCT it is important to understand the design, conduct, analysis and interpretation. This can only be achieved through total transparency and recognition of limitations encountered during the conduct of the trial. It is important to determine the quality of the methods and to avoid over interpretation of the findings.

7.3 Cost Consequence Analysis

The largest cost difference between the two types of care in the current study was accounted for by the cost of the total length of hospital stay. Additional costs incurred by the Specialist Nurse group compared with routine care included the salary of the nurse taken at midpoint “G” grade and the travel costs incurred by the Specialist Nurse from visiting patients at home. Other costs including additional theatre time, blood transfusions and antibiotics were minor and not significantly different between the groups of women. Women’s follow up care, including the number of consultations with their GP, were similar in both groups.

In this study, the Specialist Nurse group was associated with significantly lower total costs to the NHS than routine care, resulting principally from the planned reduction in the post operative length of hospital stay ($p=.0001$). A sensitivity analysis was conducted to test the robustness of the results and the extent to which the results of the analysis would hold true in a range of alternative contexts. The first part of the analysis was based on the assumption that the Specialist Nurse group may, in time, either increase or reduce the length of hospital stay by one day, and routine care would reduce length of stay by one day.

A sensitivity analysis was conducted to test the robustness of the results and the extent to which the results of the analysis would hold true in a range of alternative contexts. The sensitivity analysis showed that if length of stay was increased by one day in the Specialist Nurse group the total mean additional cost would be £57

more than for routine care. A reduction in the length of hospital stay by one day in the Specialist Nurse group could generate savings of £1530 over routine care.

The RCT showed that the Specialist Nurse care resulted in earlier discharge from the gynaecology ward. Data from the RCT suggested that the women in the routine care group tended to feel that they had been kept in hospital too long, hence the need for the sensitivity analysis on changes in length of stay. The sensitivity analysis comparing costs from all Scottish hospitals showed difficulties comparing small units and or rural units with larger urban units. Although comparing the model with the Scottish average cost of an inpatient day showed significant reduction in costs. Applying the Specialist Nurse intervention to gynaecology units in all Scottish hospitals would provide significant cost reduction in all hospitals apart from those with the lowest costs. The sensitivity analysis was particularly important because of the enormous variation in the cost of in-patient care and gynaecology costs throughout Scotland, ranging from under £200 in Uist and Barra, to over £2,500 in the Gilbert Bain hospital in Berwick. This sensitivity analysis makes a valuable contribution to the applicability of the work across Scotland and hence not restricting it to one particular care model based in the gynaecology unit at the Western Infirmary in Glasgow.

In this study, the cost per overall episode of care per patient was reduced which allowed available resources and allocated beds to be used more efficiently. An actual reduction in bed numbers was made following the study and costs were released. Four beds were removed from the bed numbers and £25,000 was released in savings, in addition to cost savings released as a result of an actual reduction in bed numbers. The salary of the Specialist Nurse was funded by vacant nursing hours that arose as a result of a reconfiguration of the ward nursing staffing levels when the new model of care was implemented. In the short term the new model of care released savings following a reduction bed reduction and also offset the cost of the Specialist Nurse's salary.

7.3.1 Economic evaluation of early discharge and hospital at home

The results of this study contrast with the only other RCT and cost minimisation study of early discharge into a hospital at home scheme in patients recovering

from a hysterectomy in gynaecology. ⁽³⁸⁾ This study was part of a larger set of randomised trials evaluating hospital at home care in a range of conditions where the authors initially thought that hospital at home schemes would contain health service costs by reducing the demand for acute hospital beds. However they found that this was not the case and hospital at home care increased health service costs for some groups of patients and showed no net difference in costs for others. These results were not surprising as patients who were discharged early to hospital at home schemes went home when their care was least expensive and hospital at home care increased the overall duration of an episode of health care. This model of care for women recovering from a hysterectomy was not cost effective.

Shepperd et al showed that early hospital discharge and transfer of care of patients into hospital at home schemes is not a cost effective alternative to acute hospital care. ⁽³⁸⁾ This study showed that combining the length of stay in hospital with the hospital at home care increased the total length of stay in the overall care episode. A subsequent review of early discharge and hospital at home care by Shepperd and Liffe did not support the development of hospital at homes services as a cheaper alternative to hospital care. ⁽¹⁵⁵⁾

The key question is about the type of “Hospital at Home” care and if the service model is designed primarily to reduce hospital days and save money? Or is it an alternative type of care designed for patients undergoing convalescence, palliative or home care, which is additional to hospital care, despite the fact that acute hospital care episode is reduced. The NHS is operating within stringent financial resources and new models of hospital discharge need to provide care of at least the same quality than current hospital care for the same or less cost.

A cost analysis from a previous observational study in women undergoing earlier hospital discharge in gynaecology following hysterectomy suggested that women could be safely discharged from hospital four or five days following abdominal hysterectomy with modest cost savings. Comparison of the mean cost difference between the groups showed that standard care cost £251 more than the shorter stay model. There were limitations in this cost evaluation, which was based on

average costs calculated for the last 24 hours before hospital discharge in both groups. The rationale given for calculating costs only in the last 24 hours was because this period was regarded as the low dependency end of hospital stay and the linear effect between initial hospital costs and intensity of care was recognised. However, the findings were not a true reflection of the actual costs and there was no sensitivity analysis conducted to test the robustness of the assumptions.

Previous studies addressed the acceptability of early hospital discharge schemes in gynaecology and point out concern about transferring the burden of care from hospital to primary care providers without a transfer of resources. However most of the studies had either inadequate or no cost analysis reported.

7.3.2 Comparison of different service models

It is important when drawing comparisons between different service models to understand the methods of service organisation adopted. Evaluation of early hospital discharge and hospital at home care needs to consider issues of service organisation, quality, outcome and cost. New models of care should not be considered in isolation from other services but should sit within the wider debate on acute care provision. Fulop recommended feasibility studies to examine organisational barriers.⁽¹⁶³⁾ Despite randomised evidence from a number of different schemes covering a range of different conditions Illife felt the RCT whilst necessary was an insufficient guide for service development and called for more descriptive studies in order to define models and improve understanding of the different types of schemes.⁽²²⁰⁾

The cost consequence evaluation conducted as part of the randomised trial in this thesis showed that the early supported discharge model of care by a Specialist Nurse is a cost effective approach for women recovering from major abdominal surgery in gynaecology. The model of early discharge in this study is different from the other two main randomised trials in this field and this model of early discharge reports significantly lower costs in comparison to routine care. This is in sharp contrast with the results of both cost minimisation studies of hospital at

home care in patients following a hysterectomy and in costs of patients with other surgical conditions. ⁽³⁸⁾ (162,221)

Studies incorporating economic evaluations in hospital at home care have increased the understanding of this type of care and highlighted the differences in schemes designed to substitute care with those providing additional quality of care for patients recovering from certain conditions. The two key economic evaluations of hospital at home care in Bristol and Northamptonshire both show a rigorous methodological approach to economic evaluation and both studies gave different conclusions. The Bristol study by Shepperd et al showed reduced costs and the Northamptonshire study by Coast had higher costs for elderly medical patients with chronic obstructive airways disease.⁽³⁸⁾ (166) The sensitivity analysis of these studies was crucial and demonstrates that the cost of the hospital at home in Bristol would exceed usual care costs even if the hospital at home were reduced by 50%, whilst a reduction of hospital at home care of only one or two days in the Northampton Study would alter the study's conclusion for one or more of the patient groups. These studies are difficult to compare and their data cannot be combined because they use different outcome measures. More importantly the results of the two studies and economic evaluation are contingent on the characteristics of local service. These studies provide useful information for service planners and show that hospital at home care can substitute for usual hospital care for some diagnostic groups. In both cases average valuations were used to estimate the resource used per patient. The level of detail about hospital resources available for individual patients was relatively low in both studies and the cost of hospital care was an average cost of inpatient care.

The NHS is under increasing public scrutiny and is continually seeking new and improved ways of delivering services to patients. The early discharge model of care adopted in this study, significantly reduced the length of hospital stay and had no adverse impact on the health status and recovery of women receiving this type of care. Planned early discharge by a Specialist Nurse is a cost effective common sense approach avoiding the problems of unplanned discharges for patients. This model of care is associated with significantly greater levels of

patient information on post-operative recovery and return to normal activities and the provision of lifestyle information and advice given which was shown to be an effective intervention by the Specialist Nurse.

7.3.3 Methodological limitations of the economic evaluation

Clinical and economic evaluation of early discharge and hospital at home schemes have shown a number of difficulties and limitations partly because of the heterogeneity of schemes but also because of the different organisational processes and barriers to this type of care.

Difficulties of the small sample size and the limitation of failing to reach the planned sample size have been addressed in the RCT. Studies that seek to reduce and examine the length of hospital stay have shown a tendency to emphasise the fact that it is desirable to reduce periods of hospitalisation, although the social costs of earlier hospital discharge have tended to be under estimated and the savings over estimated.⁽³⁹⁾ The economic evaluation did not examine costs from the patient or societal perspective, which is one of the basic principles of economic evaluation in health care. The reason for this was because there was insufficient manpower available to collect this data. This study had no funding available for research staff apart from the independent research nurse who came from another department to administer the study questionnaires.

A reduction in one day in the length of stay means a cost saving equivalent to the average cost of one day in hospital. There were limitations of the economic evaluation, with the one factor being that average valuations were used to estimate the inpatient stay and these were taken from the published NHS hospital costs. The level of detail about hospital resources available for individual patients was relatively low in both groups.

There have been few adequate economic evaluations and studies of economic benefits have been found to be small because reductions in length of stay rarely represent reductions in the intensity of services provided. Reductions in length of stay may increase the intensity of care provided in the ward, although this is dependent on utilising free nursing capacity so that work can readily be

redistributed without adversely affecting the quality of the care provided.⁽³⁹⁾ The costs of a day in hospital were calculated from the Scottish Health Manual, which does not take account of the diminishing costs associated with the number of days in hospital. The non-linear relationship between the cost and intensity of care immediately following surgery recognised that the intensity of care falls off in the majority of patients undergoing major elective surgical procedures 2 – 3 days postoperatively. If the linear effect of hospital costs and intensity of care were applied the savings for length of stay reduction may have been lower. However, it has not been possible to apportion accurate costs to individual post operative days in either model. The sensitivity analysis conducted within the economic evaluation was designed to address this and demonstrated the change in financial savings within a range of different scenarios throughout Scotland.

In the cost analysis and comparisons made for this thesis inpatient day costs have been averaged. The number of nurses and medical staff that were required to run the gynaecology ward remained static in each 24 hour period. This was regardless of the level of workload and there was no reduction or increase in the overall number of staff on the costs between days of care. The theatre usage was similar in each group and it was not possible to estimate how much of the theatre costs were included in the calculation of the difference in average day costs. The hotel costs and overheads were small. None of the women required admission to ITU in either group. A pragmatic approach was taken to measure the main cost differences between both types of care. Resources in terms of diagnostic tests, operating time, GP home visits, were minimal, hence the resource for each of these items is not reported. Use of opiates for pain control was not recorded as a previous study held in the same unit showed no difference in the analgesic requirements of two patients undergoing abdominal hysterectomy and laparoscopic hysterectomy.⁽¹⁴⁸⁾ This information was not collected, as the two groups in the study were very similar.

A cost consequence analysis of the main differences was conducted with the randomised trial in this thesis and the costs were estimated and valued using 2003-04 prices and the consequences of both models of care were examined. The approach used in the cost consequence evaluation differs from the approach taken

in the cost minimisation study comparing “hospital at home care” with acute hospital care in a range of conditions including hysterectomy. Shepperd used dependency evaluation methods to adjust for the non-linear relationship between the cost of care and its intensity with most care provided at the early part of the admission.⁽³⁸⁾ It has been recognised that subjective evaluation is problematic in its self and the BMJ guidelines on economic evaluation discourage this type of scoring judgement because of the potential to introduce bias, and because assumptions can either reduce or increase the cost of care. In order to try and get round this, attempts were made to ensure the same method of quantifying hospital costs was used in both groups to identify any additional costs incurred by those undergoing early discharge.

There is a question as to how far it is desirable to cut down the period of hospitalisation. A general reduction in the length of hospital stay releases resources which can be used for treating a greater number of patients. A common misconception is that reductions in length of stay can lead to a corresponding reduction in hospital waiting lists for surgery. However, changes in waiting lists are also affected by the number of theatre sessions available for use.

Chapter 8 -Conclusions of the studies within the thesis

The thesis had two aims. These were: 1) to evaluate, by a randomised controlled trial, Specialist Nurse led early hospital discharge and compare this with routine care following major surgical treatment for benign gynaecological conditions 2) to compare the costs and consequences of both types of care.

The development of Specialist Nurses was traced in the literature in historic and political context and parallel evolution internationally. The difference between extension and expansion of nursing roles was highlighted and attention to the confusing array of titles used to describe advanced nursing practice roles. The difficulties involved in evaluating the role of the Specialist Nurse were explored and the complicating factors in defining outcomes highlighted. The potential important contribution that Specialist Nurses can make to service provision was highlighted.

The thesis successfully achieved its first aim. The results of the study showed significant improvement in the health status of both groups of women following gynaecological surgery. The follow up paired mean scores were improved in six of the eight SF-36 dimensions; including physical functioning, pain, emotional and mental health, energy/vitality and general health perception, the same in both groups. Reduction in the length of hospital stay was part of the Specialist Nurse planned intervention and new model of care.

The women in the Specialist Nurse group had significantly shorter length of hospital stay than those in routine care. The mean post operative length of hospital stay in the Specialist Nurse Group was 3.38 days compared with a mean of 4.87 days for women in the Routine Care Group. Women undergoing both types of care showed no significant difference in their reported symptoms at hospital discharge and at 6 weeks post operatively. Women in the Specialist Nurse group did not report any adverse effects as a result of earlier hospital discharge. Women's satisfaction with specific information regarding recovery and return to normal was greater in the Specialist Nurse Group than in the Routine Care Group.

In addition the Specialist Nurse Group received general lifestyle advice not usually given to women in the Routine Care Group.

The second aim and cost comparison of the new model of care with conventional care was achieved. The economic evaluation was conducted as a sub study of the randomised controlled trial and the approach used was a cost consequence analysis. There was a significant potential for cost savings as a result of early hospital discharge with support from a Specialist Nurse. Such savings were primarily based on the reduction of hospital inpatient stay. The cost per overall episode of care per patient was reduced, which allowed available resources and allocated beds to be used more efficiently. In this case an actual reduction in bed numbers was made following the study. Four inpatient beds were removed with costs were released. There were significant financial savings made in the gynaecology unit for the hospital as a result of shorter length of stay and implementation of the new model of care. The cost of the Specialist Nurse's salary was met by the release of savings.

The non linear relationship between the cost and intensity of care immediately following surgery was recognised. If the linear effect of hospital costs and intensity of care were applied the savings for the reduction in the length of hospital stay would have been lower. This was recognised and the sensitivity analysis was designed to support changes in length of hospital stay. Conversely, it should be noted that during the trial the Specialist Nurse was not working at full capacity. There was therefore potential to further reduce the costs by increasing the number of women in the intervention group receiving care from the Specialist Nurse.

There were limitations in the economic evaluation in that not all of the costs were calculated at the point of the patient as a pragmatic approach was taken to measure the main cost differences between each type of care. More importantly it was recognised that the economic evaluation did not examine the costs from the patient or societal perspective and this should be incorporated in future studies of this kind.

There are few controlled studies of changes in models of health care and costs. Prior to this study, no randomised controlled trials have evaluated the effectiveness and cost of early hospital discharge following total abdominal hysterectomy and major pelvic surgical procedures with support from a Specialist Nurse. The results of the randomised controlled trial show the length of hospital stay can be safely reduced with support from a Specialist Nurse in gynaecology. Care at home does not give rise to poorer outcomes or delay in recovery in respect of physical and psychological health status measures. Women who were discharged as early as two days after major gynaecological surgery had similar outcomes to those staying longer. There were few differences found in outcomes between the two groups of women in the study. The two groups of women in the study showed similar clinical, social, employment and demographic characteristics.

The study showed that there was no transfer of care from the hospital to the community. This may have been in part because the model of care was specifically designed to support self care and convalescence at home. The women in the intervention Group were encouraged to seek advice from the Specialist Nurse if required. A recognised limitation of the study was the lack of data from the General Practitioner regarding patient's follow up and the potential transfer of care as a result of earlier hospital discharge.

Evidence of the effect of Specialist Nurses on the development of new services and outcome of care for patients is scant in the gynaecology setting. There were limitations in the questionnaire designed to capture milestones of recovery and in the relatively short term follow up which was chosen specifically to identify any effects of early hospital discharge. There were problems with the randomised controlled trial which did not achieve its estimated sample size. However, the study was able to show that a new model of care and early hospital discharge on the second post-operative day had no adverse effect on the women's quality of life and was an acceptable and cost efficient method of care. Earlier hospital discharge at 48 hours after major abdominal and pelvic surgery is an acceptable,

cost effective alternative to current routine practice in the absence of further randomised evidence.

8.1 Recommendations

Shorter hospital stay has been shown to have no adverse effect on health status and is safe and acceptable following major gynaecological surgery. Adequate information and preparation of patients prior to surgery is required to facilitate shorter periods of hospitalisation. It is unclear the extent to which these results can be extrapolated to other major elective surgery. This study showed that Specialist Nurse care resulted in earlier discharge from the gynaecology ward and that this model of care was a cost effective approach. The sensitivity analysis showed an enormous variation in the cost of inpatient care in gynaecology units throughout Scotland and the potential to reduce costs and implement the model in other units should be explored.

A potential advantage of shorter length of stay is increased efficiency. Previous economic benefits have been found to be small because reductions in length of stay rarely represent reductions in the intensity of services provided. This model of care facilitated earlier hospital discharge based on individual patient need and showed that women could be safely discharged early without any detrimental effect to their health or need for post discharge care.

Reduction in length of hospital stay can produce a faster throughput of patients from the waiting list, hence reducing the average time spent waiting for admission, or it could lead to a reduction in the number of beds required to cope with the existing throughput. Other factors including theatre times and allocated operating sessions influence such decisions and in this case a combination in reduction in the total number of beds and improved patient throughput resulted. All of these factors require to be considered in future studies involving reductions in length of stay following surgery. When suggesting changes to established service models, economic evaluation should be carried out to compare the cost of care before changes to the service are made.

The NHS is operating within stringent financial resources and new models of hospital discharge need to provide care of at least the same quality than current hospital care for the same or less cost.

Development of Specialist Nurse roles, as used in this study, can offer an alternative model to managing elective surgery. This has implications for throughput of patients with theatre and bed planning issues offering cost and waiting list benefits. These complex issues require to be explored further when planning future models of care in a surgical setting.

Specialist Nurses offer the opportunity to improve health information and lifestyle advice. The provision of individual patient information and lifestyle advice allows greater self-responsibility and adds to both public and social health improvements.

The role of the Specialist Nurse in the provision of direct patient care should be defined, evaluated and compared with standard practice. Further studies demonstrating the effects of Specialist Nurse intervention are required on a specialty by specialty basis.

There is a need to develop the case for the establishment of new nursing roles that are based on health care need and impact on existing services.

Chapter 9 - References

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Appendix 1

Multifile Search: CINAHL 1982-December 2005, Medline 1966 – December 2005, Embase 1980 – December 2005.

#	Search History	Description	Results
1		exp CNS/	8281
2		exp nursing/	172341
3		(clinical adj2 specialist\$.tw. and 2	817
4		exp advanced nursing practice/	6900
5		(advanced adj2 practice).tw. and 2	944
6		exp NP/	19451
7		((extended adj3 (role\$ or practice)) and nurs\$).mp.	400
8		1 or 3 or 4 or 5 or 6 or 7	32756
9		exp gynecologic care/	473
10		exp Gynecology/	12558
11		exp gynecologic nursing/	264
12		(gyn?ecolog\$ adj2 nurs\$).tw.	336
13		exp genital diseases, female/	468324
14		exp surgery, gynecologic/	42495
15		exp gynecologic surgery/	90235
16		or/9-15	532595
17		8 and 16	458
18		remove duplicates from 17	415
19		exp patient discharge/	60023
20		exp discharge planning/	12982
21		exp hospital discharge/	14664
22		exp early patient discharge/	541
23		exp "length of stay"/	53521
24		exp home health care/	18122
25		((earl\$ or support\$) adj3 discharge\$).tw.	6762
26		or/19-25	137913
27		8 and 26	795
28		remove duplicates from 27	728
29		16 and 26	3361
30		remove duplicates from 29	3025
31		sf-36.it.	2867
32		sf36.it.	27
33		short form\$.it.	4049
34		(sf36 or sf-36 or (short adj form)).tw.	18895
35		or/31-34	18899
36		8 and 35	54

37	remove duplicates from 36	49
38	16 and 35	348
39	remove duplicates from 38	256
40	exp health care costs/	108440
41	exp "cost benefit analysis"/	63059
42	((cost\$ or mone\$ or revenue\$ or budget\$ or economic\$) adj3 (effective\$ or benefit\$ or analys\$ or outcome\$ or consequence\$)).tw.	118841
43	or/40-42	235320
44	8 and 43	1262
45	remove duplicates from 44	1027
46	16 and 43	6375
47	journal article.pt.	13969256
48	article.pt.	4694910
49	47 or 48	18664166
50	46 and 49	4073
51	remove duplicates from 50	3328
52	26 and 43	15148
53	49 and 52	11526
54	limit 53 to yr="1902 - 1999"	5528
55	remove duplicates from 54	4742
56	53	11526
57	limit 56 to yr="2000 - 2006"	5998
58	remove duplicates from 57	4993
59	55 or 58	9735
60	(8 or 16) and 26 and 43	544
61	remove duplicates from 60	478

Database: EBM Reviews - Cochrane Database of Systematic Reviews <4th Quarter 2005>

Search Strategy:

-
- 1 (hospital adj2 home).mp. [mp=title, abstract, full text, keywords, caption text] (121)
 - 2 (obstetric\$ or gyn?ecolog\$ or neonat\$ or paediatric\$ or pediatric\$ or midwi\$).mp. [mp=title, short title, abstract, full text, keywords, caption text] (1529)
 - 3 1 and 2 (57)
 - 4 limit 3 to systematic reviews (49)
 - 5 from 4 keep 2-5,13-14,16,26,49 (9)
 - 6 ((early or supported) adj2 discharg\$).mp. [mp=title, short title, abstract, full text, keywords, caption text] (65)
 - 7 2 and 6 (34)
 - 8 7 not 3 (28)
 - 9 limit 8 to systematic reviews (24)
 - 10 ((specialist or practitioner) adj nurs\$).mp. [mp=title, short title, abstract, full text, keywords, caption text] (33)
 - 11 from 10 keep 13 (1)
 - 12 5 or 11 (9)
 - 13 from 12 keep 1-9 (9)

GYNAECOLOGY WESTERN INFIRMARY GLASGOW

ROUTINE GYNAECOLOGY NURSING CARE FOR ABDOMINAL AND PELVIC SURGERY

Admission day

1. Seen by named nurse, personal details and baseline observations documented
2. Information given verbally re:
 - Skin preparation
 - Bowel preparation
 - Fasting
 - PCA
 - IVI
 - Urinary catheter
 - How to get in/out of bed post operatively

Theatre day

Routine pre/post operative care

i.e. TPR, BP, wound care, IV fluids, DVT prophylaxis, pain control with PCA

Post operative day 1

1. Pain control IV/IM/Oral
2. Encourage early mobilisation
3. Encourage fluids and diet
4. Remove IVI/PCA if necessary
5. Wound are
6. Assistance with personal hygiene

Post operative day 2

1. Pain control oral
2. Encourage mobilisation
3. Fluids and diet
4. Wound care
5. 4 hourly TPR and BP
6. Assistance with personal hygiene

Post operative day 3

1. Pain control
2. Encourage mobility
3. Wound observation
4. Fluids and diet
5. Daily TPR

Post operative day 4

1. Pain control
2. Wound observation
3. Daily TPR
4. Preparation for discharge – discharge prescription

Post operative day 5 & 6

1. Clips/staples removed
2. Discharge advice given re lifting and handling, housework, driving, sexual intercourse
3. Information given re analgesia and HRT if appropriate
4. Information given re follow-up appointment

**I Traynor, Gynaecology Sister
1999/2000**

GYNAECOLOGY WESTERN INFIRMARY GLASGOW

**GYNAECOLOGY SPECIALIST NURSE SUPPORTED DISCHARGE FOR MAJOR
ABDOMINAL AND PELVIC SURGERY FOR BENIGN DISEASE**

Pre admission

Information was given to women on the service and support available from the specialist nurse including what to expect on admission to hospital. An information leaflet including specialist nurse contact details and telephone number were issued to the women.

Admission day

1. Seen by specialist nurse and given verbal information about:
 - Operative procedure and preparation for surgery
 - Ward nurse information reinforced
 - Information about what to expect post-operatively
 - Information about discharge and support arrangements

Post operative day 1

1. Seen by specialist nurse and given information about:
 - Mobilisation and activity
 - Fluids and diet
 - Pain control advice
 - Discharge home

Post operative day 2

1. Seen by specialist nurse, assessment and review of condition
2. Advice given about:
 - Mobilisation and activity
 - Fluids and diet
 - Pain control
 - Wound (if appropriate)
 - Bowel and bladder function
 - Discuss discharge plan for day 3
3. Health and lifestyle advice given by specialist nurse on:
 - Smoking
 - Alcohol intake
 - Breast screening and breast examination leaflet given
 - Osteoporosis advice
 - Advice on HRT
 - Exercise
 - Return to work
 - Commence sexual relations
 - Driving
 - Housework heavy lifting

Post operative day 3

1. Seen by specialist nurse, assessed for discharge and advice given:
 - Coping at home
 - Pain control at home
 - Adequate rest and resumption of physical activity
 - DVT advice how long to keep T.E.D. stockings in situ and leg exercises
 - Discharge drugs given and explained
 - Health and lifestyle advice reinforced
 - Specialist nurse will telephone at home the following day
 - Contact details given and follow-up arrangements including liaison with GP made

**T Docherty, Gynaecology Specialist Nurse
1999/2000**

ASPECTS OF YOUR HEALTH SF-36

Study Number

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The following questions ask for your views about your health and how you feel about life in general. If you are unsure about how to answer any question, try and think about your overall health and give the best answer you can. Do not spend too much time in answering as your immediate response is likely to be the most accurate.

1. In general would you say your health is?
- Excellent

Very good

Good

Fair

Poor
- ☐5

☐4

☐3

☐2

☐1

2. Compared to one year ago, how would you rate your health in general now?
- Much better than one year ago

Somewhat better now than one year ago

About the same

Worse now than one year ago

Much worse now than one year ago
- ☐5

☐4

☐3

☐2

☐1

3. The following questions are about activities you might do during a typical day. Does your health limit you in these activities? If so, how much?

	Yes limited a lot	Yes limited a little	No, not limited at all
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
ii. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
iii. Lifting or carrying groceries.	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
iv. Climbing several flights of stairs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
v. Climbing one flight of stairs	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
vi. Bending kneeling or stooping	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
vii. Walking more than one mile	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
viii. Walking half a mile	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
ix. Walking 100 yards	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
x. Bathing and dressing yourself	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

		No
i. Cut down on the amount of time you spent on work or other activities	<input type="radio"/>	<input type="radio"/>
ii. Accomplished less than you would like	<input type="radio"/>	<input type="radio"/>
iii. Were limited in the kind of work or other activities	<input type="radio"/>	<input type="radio"/>
iv. Had difficulty performing the work or other activities (e.g. it took extra effort)	<input type="radio"/>	<input type="radio"/>

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

		No
i. Cut down on the amount of time you spent on work or other activities	<input type="radio"/>	<input type="radio"/>
ii. Accomplished less than you would like	<input type="radio"/>	<input type="radio"/>
iii. Didn't do work or other activities as carefully as usual	<input type="radio"/> 2	<input type="radio"/> 1

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?

Not at all	<input type="radio"/> ₅
Slightly	<input type="radio"/> ₄
Moderately	<input type="radio"/> ₃
Quite a bit	<input type="radio"/> ₂
Extremely	<input type="radio"/> ₁

7. How much bodily pain have you had in the past 4 weeks?

- None ☐ 6
- Very mild ☐ 5
- Mild ☐ 4
- Moderate ☐ 3
- Severe ☐ 2
- Very severe ☐ 1

8. During the past 4 weeks, how much did pain interfere with your normal work (including work both outside the home and housework)?

- Not at all ☐ 5
- A little bit ☐ 4
- Moderately ☐ 3
- Quite a bit ☐ 2
- Extremely ☐ 1

9. These questions are about how you feel and how things have been with you during the past month. (For each question please indicate the one answer that comes closest to the way you have been feeling).

How much time during the past month.....		All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
	Did you feel full of life?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
ii.	Have you felt particularly nervous?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
iii.	Have you felt so down in the dumps that nothing could cheer you up?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
iv.	Have you felt calm and peaceful?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
v.	Did you have a lot of energy?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
vi.	Have you felt downhearted and miserable?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
vii.	Did you feel worn out?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

Question 9. continued

How much time during the past month.....	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
viii. Have you been happy?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
ix. Did you feel tired?	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
x. Has your health limited your social activities (like visitng friends or close relatives)?	<input type="radio"/> 6	<input type="radio"/> 5	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1

10. Please choose the answer that best describes how true or false each of the following statements is for you.

	Definitely true	Mostly true	Not sure	Mostly false	Definitely false
i. I seem to get ill more than other people	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
ii. I am as healthy as anybody I know	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
iii. I expect my health to get worse	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
iv. My health is excellent	<input type="radio"/> 5	<input type="radio"/> 4	<input type="radio"/> 3	<input type="radio"/> 2	<input type="radio"/> 1

...End of questionnaire....

WEST GLASGOW HOSPITALS UNIVERSITY NHS TRUST

THE WEST ETHICAL COMMITTEE
APPLICATION TO THE ETHICAL COMMITTEE FOR
APPROVAL OF A CLINICAL RESEARCH PROJECT

Please read these guidelines before completing the proforma. You are also advised to refer to the document "Working with your Ethics Committee". *

1. One typed copy of this application must be submitted to Secretary, West Ethics Committee, Western Infirmary, no later than 4pm on the Monday two weeks preceding the meeting of the Committee: the Committee meets on the first and third Tuesday of each month. Late arriving protocols will not be considered until the next meeting.
2. All of the numbered headings must be addressed. Protocols must be presented in a concise manner with additional pages only being used if absolutely essential. Protocols presented in any other format or which deviate substantially from our guidelines in Working with your Ethics Committee will not be considered.
3. All investigators must sign the supporting Declaration Section 10). Copies of the complete Declaration of Helsinki are available from the Secretary West Ethics Committee. The principal investigator must complete Section 11 if the research project involves participation of healthy volunteers. Copies of the Report "Research on Healthy Volunteers", Royal College of Physicians of London, are available from the Administrator's office.
4. A patient/volunteer consent form must accompany all protocols and must pay heed to the advice given by the Committee on the inclusion of certain standard phrases.
5. The investigators must not recruit medical and nursing students to participate as research volunteers.
6. Protocols will fall from the agenda if information is not forthcoming within 3 months of requests being made by the Committee.
7. **Grants/Charges:** See Attached Sheet

Company ☐ Charity ☐ Non-funded ☒

8. Is this project Multi-centred i.e. taking place in 5 or more UK centres ☐ Yes ☒ No
(See attached sheet)

1. **Brief Title of Project:**

A randomised controlled trial comparing specialist nurse supported discharge with routine care.

2. **Name, Grade and Personal Qualifications of Investigators.**

Heather Dawes, MPH, RGN, RM
 Dr R Knill-Jones, Senior Lecturer in Epidemiology, Department of Public Health
 Dr D H Gilmore, Consultant Gynaecologist
 Dr M A Lumsden, Senior Lecturer, Obstetrics and Gynaecology
 Sr T Docherty, Specialist Nurse

Approved by: (If non of the investigators is a Consultant in the appropriate department)

3. **Purpose of Study:** (Please outline the background of the work, what information you hope to obtain and what you believe will be benefit to the patient and/or to medical science)

It is generally accepted that nurses make a substantial contribution to promoting health and wellbeing with groups and individuals. Radical changes in the shape and delivery of acute hospital services are evident. Changes in clinical practice and improved technology have resulted in a growing number of patients being cared for in local care settings that are often nurse led. It is now apparent that the development of any new and innovative nursing roles should be supported by research in the need to ensure that nursing resources are effectively utilised.

The idea to develop the Specialist Nurse run Supported Discharge service for women in Gynaecology came about because of the changing nature of service in gynaecology. Both medical and nursing staff feel that women can go home earlier if adequate home support is available. Support from a Specialist Nurse may be one way of achieving this.

Monies were released by service redesign for a Specialist Nurse to develop and run a Supported Discharge Programme for women in Gynaecology. The service will consist of dedicated specialist nurse assessment, implementation of discharge planning process, advice and follow up. However, it is important to assess the benefit of such a service against routine care. The service aims to reduce the length of stay in hospital and reduce the use of hospital beds with an ultimate reduction in costs to the Health Service. This proposed innovation in service delivery is thought to be an improvement to the patient and the existing service provision. Some of the proposed benefits to patients include: the provision of dedicated care and advice from a specialist nurse, reduction in the length of time spent in hospital and participation in a structured discharge planning process.

There is a need to maximise the utilisation of inpatient hospital beds. The increased provision of services in the community is one proposed method of reducing the pressure on acute hospitals. There is evidence that some groups of patients want to get home earlier and spend less time in hospital. From a recent inpatient survey in gynaecology 63.3% (n=19) of women would have liked to go home earlier if they had direct contact to an identified nurse from the hospital who could visit them at home. Eighty Six percent (n=26) of the women surveyed would like to have talked with a Gynaecology specialist nurse before discharge home from hospital.

There is growing interest in applying the methods of randomised controlled trials to issues in delivering health services. A randomised controlled trial will assess the effectiveness of the nurse practitioner role in gynaecology and avoid only introducing the new service to those expected to benefit.

The endpoints of the study are to identify if the use of a Specialist Nurse run Supported Discharge service will reduce the length of hospital stay. The Average length of stay for hysterectomy is 6.3 days. The study will aim to produce a cost benefit analysis of new and routine care and to identify both patient and staff satisfaction with the new service.

4. **Details of Procedure:** (Explain how the study will be executed including details of recruitment, treatment allocation, procedures undertaken and study visits).

Consent to randomisation will be sought at the gynaecology outpatient clinics from all women booked for elective surgery for benign gynaecology disease.

Initially we will approach the whole population going through the new service (approximating 30 per month). Following consent, patients will be randomly allocated to supported discharge or routine care. We intend to recruit 100 women sequentially to the study over a period of six months commencing November 1998 the start point of the new service. Women will be followed up by Questionnaire at six weeks and the analysis of the six month sample will be complete by twelve months.

Routine Care

- a) Patients who receive routine care will be followed up by questionnaires at six weeks following discharge.

The high standard of routine care currently delivered by the gynaecology service will be maintained throughout the study period.

Supported Discharge

- a) Patients will meet the Gynaecology Specialist Nurse prior to surgery at which point patient information will be given and the discharge plan will be initiated and documented.
- b) Arrangements will be planned for discharge on day three post operative
- c) This will be determined by a pre discharge assessment, carried out by the Nurse Practitioner
- d) Following discharge on the first day home (4th post op day) the women will receive a telephone call from the Nurse Practitioner who will also visit if necessary.
- e) The Nurse Practitioner will visit women routinely on the 5th post op day. Sutures or clips may be removed during this visit.
- f) Further Home visits will be determined by individual patient needs.
- g) Women will be discharged from Nurse Practitioner Care approx Day 10 and the patients GP will be informed by standard letter
- h) Women will receive a follow up visit and questionnaires six weeks following discharge from the supported discharge scheme.

5. **Facilities and Personnel to support the work:** Indicate here how the facilities and personnel you have available will enable the project to be adequately executed).

Heather Dawes, Directorate Nurse Manager who is currently Registered for MSc/PhD with the Department of Public Health Medicine, University of Glasgow, will take responsibility for the study. The agreed research commitment: 8 – 12 hours per week.

The Study will be supervised by Dr Robin Knill-Jones, Senior Lecturer in Epidemiology from the Department of Public Health Medicine, University of Glasgow.

Sister Teresa Docherty, Nurse Practitioner Gynaecology: Is now employed in a new funded full time post 37.5 hours per week.

Travelling expenses have been included.

- Office space – interview room Ward G9 (adequate)
- Secretarial support 4 hours per week
- Existing secure PC
- Windows 95 software
- Printer

6. **Patient/Volunteers:** (Please indicate how patients and/or volunteers are chosen giving the numbers chosen and justification for these numbers with power calculations where appropriate. Entry and exclusion criteria should be clearly stated. Particular regard should be paid to the status of women of child-bearing age).

Consent to randomisation will be sought from all women who are admitted to Ward G9 Gynaecology for elective surgery for benign gynaecological disease.

Exclusion Criteria

- a) They live more than 25 miles (40km) away from the hospital
- b) They do not have telephone access at discharge destination
- c) They have present of another major illness, which is likely to dominate the pattern of care example advanced cancer, renal failure
- d) Presence of significant physical and/or social barriers as determined through professional assessment by Consultant and/or nurse.

Aim of Study

To determine whether supported discharge leads to a decrease in hospital stay.

Power Calculation

25 women per group give an 85% power to detect a difference in hospital stay of 2 days at the 5% level. Based on length of stay from an unpublished study by Dr M A Lumsden. Calculation by Mr T Aitchison, Department of Biostatistics, University of Glasgow.

Review of an existing data set 1st October 97 – 31st March 98 enabled a projection of the annual/monthly rate of elective cases coming through the ward. Projected at 400 per year. Expected 28 per month with refusals. A variation in the number per month is expected. Patients who consent to take part in randomisation will be put through broad entry inclusion criteria for assessment of eligibility.

Inclusion Criteria

- They do not live more than 25 miles (40km) away from the hospital
- They have telephone access at discharge destination
- They do not have presence of another major illness, which is likely to dominate the pattern of care example advance cancer, renal failure
- Absence of significant physical and/or social barriers as determined through assessment by Consultant and/or nurse

Those who do not meet the eligibility criteria will be allocated to routine care.

Those who meet the eligibility criteria will be randomly allocated to either routine care of Supported Discharge.

Randomisation Methodology

All consenting women will be allocated a random number generated by computer. Each sequential block of ten women will then be sorted according to the random number generated. They will be put into sealed envelopes with the first five then being allocated to routine care and the second five allocated to supported discharge.

7. Drugs, dosages and non-standard products: (Please include all drugs. If a new drug is to be used a copy of the Clinical Trials Certificate of Clinical Trials Exemption Certification from the Committee on a Safety of Medicines must be attached).

Not Applicable

8. Safety: (Please state briefly the known pharmacology of the drugs used indicating side effects and toxicity, together with hazards of any invasive procedure performed). The minimum information would be that contained in the British Formulary

Not Applicable

9. Radioactive Substances: (If radioisotopes are to be used, details of premises clearance by Radiation Protection Officer should be given and certificate of registration with the DHSS must be attached. The approximate dose of radioactivity administration should be stated).

Not Applicable

West Glasgow Hospitals University NHS Trust

Our Ref: AHT/JR

Your Ref:

Please reply to: Mrs A H Torrie
SECRETARY - WEST ETHICS COMMITTEE

WEST ETHICS COMMITTEE

Western Infirmary
Dumbarton Road

Glasgow G11 6NT

Direct Line: 211 6238
Fax: 211 1920

26th October 1998

Mrs Heather Dawes
Nurse Manager
Surgical Specialties & Nephrology Directorate
Western Infirmary
Glasgow

Dear Heather,

Protocol No.98/194(2) - A randomised controlled trial comparing specialist nurse supported discharge with routine care.

The Committee at its meeting held on 20th October, 1998 discussed the above study and required the undernoted clarification/amendments to be made:

- a) The Committee felt that you should record how many patients are being screened for the study.
- b) The Committee would like sight of the questionnaire to be used.
- c) The Committee felt that patients should be contacted prior to coming into hospital and consented at this time also.
- d) The Committee also felt that it should be stated that the primary end point is the cost benefit analysis.

A contact name and telephone number should be added to the Patient Information Sheet. The above amendments/clarifications should come to the Secretary for filing. This study has full Ethics Committee approval.

With kind regards.

Yours sincerely,



Andrea H Torrie

SECRETARY WEST ETHICS COMMITTEE (2)

Incorporating the Western Infirmary, Gartnavel General Hospital,
The Glasgow Homoeopathic Hospital, Drumchapel Hospital and Blawarthill Hospital



THIS SHEET HAS BEEN APPROVED BY THE WEST ETHICS COMMITTEE

INFORMATION SHEET FOR PATIENTS/VOLUNTEERS IN CLINICAL RESEARCH PROJECT

Brief title of project

A randomised controlled trial comparing specialist nurse supported discharge with routine care.

Patient's summary (Purpose of study, nature of procedure, discomfort and possible risks in terms which the patient or volunteer can understand).

We would like to invite you to take part in a study that aims to evaluate a new specialist nurse supported discharge service. This new service will be compared with the existing discharge planning service. This study will be randomised which means that you have a 50:50 chance of allocation to either group.

What This Means to You

Routine Discharge Service:

If you are allocated to this group you will receive the current high standard of care provided by our existing discharge planning service. The discharge date will be decided by the doctors in charge of your care and will usually be about 5 – 7 days following a procedure involving an operation. Six weeks following discharge from routine care you will receive a follow-up visit where you will be invited to complete a questionnaire.

Supported Discharge Service

If you are allocated to the new Supported Discharge Service you will meet the Gynaecology Specialist Nurse before you have your operation where you will be given information on what to expect following surgery, your discharge plan will be initiated and documented. Arrangements will be planned for your discharge on the third day after your operation. This will be determined by a pre-discharge assessment, carried out by the Specialist Nurse.

On the first day home following discharge usually the 4th day following your operation you will receive a telephone call from the Gynaecology Specialist Nurse who will also visit you at home if necessary. Sutures or clips may be removed during this visit. Any further home visits will be determined by yourself and the Specialist Nurse. You will be discharged from Specialist Nurse care on around day 10 following surgery.

At 6 weeks and 12 weeks following discharge from the supported discharge scheme you will receive a follow-up visit where you will be invited to complete a questionnaire.

You are under no obligation to take part in this study which may not be of benefit to you and refusal to participate would not alter the treatment that you would normally receive. Notice will be sent to your General Practitioner about your participation. You may withdraw at any stage or refuse to answer questions if you wish. All information given in the Questionnaires will remain completely confidential. If you do not feel ready to go home on Day 3, you will not be compelled to do so.

You will be informed of which group you have been allocated to before your admission to the ward.

If you have any questions Teresa Docherty, Clinical Nurse Specialist can be contacted by telephone 0141 211 2915

WEST ETHICS COMMITTEE

FORM OF CONSENT FOR PATIENTS/VOLUNTEERS IN CLINICAL RESEARCH PROJECT

Title of Project:

A randomised controlled trial comparing specialist nurse supported discharge with routine care.

By signing this form you give consent to your participation in the project whose title is at the top of this page. You should have been given a complete explanation of the project to your satisfaction and have been given the opportunity to ask questions. You should have been given the opportunity to ask questions. You should have been given a copy of the patient information sheet approved by the West Ethics Committee to read and to keep. Even though you have agreed to take part in the research procedures you may withdraw this consent at any time without the need to explain why and without any prejudice to your care.

Consent:

I (PRINT)

of

give my consent to the research procedures above, the nature, purpose and possible consequences of which have been described to me

by RESEARCH NURSE

Patient's signature Date

Nurse's signature

Eligibility Assessment

Name:

Address:

Unit Number:

D.O.B:

Home Tel. Number:

Operation:

Consultant:

All women (consenting or not) must be put through the eligibility assessment to identify whether women:

1.

Live more than 25 Miles (40km) away from hospital

Yes

☐

No

☐
2.

Have telephone access at discharge destination

Yes

☐

No

☐
3.

Have presence of another major illness, which is likely to dominate the pattern of care e.g. renal failure

Yes

☐

No

☐

If yes, please state

4.

Have presence of significant physical and or social barriers as determined through assessment by Nurse of Consultant

Yes

☐

No

☐

If yes, please state

5.

Does this women meet eligibility criteria?

Yes

☐

No

☐

If yes, pass on to randomisation process.

If no, please state

Assessment Completed By: Name: Signature:

Gynaecology Nursing Service

Name: Address: Post code Tel. No		Admission date: Theatre date: Discharge date: Post OP day: Elective Emergency Consultant:	
General Practitioner		GP Address	
Surgery performed		GP Tel. No. GP Fax No.	
Parity	DOB Age	Unit Number	
Single Married Widowed Divorced Separated		Number of children at home: Age(s):	
Lives alone Husband Partner Children Parents Give details of any home support available? Give details home support arranged?		Occupation: Currently employed YES NO Full time Part time Retired	
At any time during this admission, have you had a urinary catheter inserted? YES NO Give reason for insertion? Date insert Date removed Has a urine C&S been taken? YES NO If Yes was result: Positive/Negative Was treatment commenced? YES NO Please state including date:		State other conditions such as: Diabetes, Asthma Complications since surgery:	
Please record condition of wound/perineum Satisfactory Inflammation Has a wound swab been taken? YES NO If yes was result: Positive/Negative Was treatment commenced? YES NO Please state including date: Sutures/clips removed Date: _____ Post Op day: _____		Are you taking HRT? YES NO If Yes, what are you taking? When was HRT started? Who started HRT and why? Do you always take your HRT? YES NO	

PILOT QUESTIONNAIRES

1. How would you rate your general health, compared with other women your age?

- Worse than most ☐
- About the same as others ☐
- Better than most ☐

2. Do you work? *Please tick*

- Yes, Full Time ☐
- Yes, Part Time ☐
- No ☐
- Retired ☐

3. How many babies have you had? _____/_____

4. Do you take regular exercise?

- Yes ☐
- No ☐

If yes, please describe:

5. Do you carry out breast examination?

- Yes ☐
- No ☐

6. Have you ever Smoked regularly? Please tick one

Never smoked ☐

Used to smoke

☐

Still smoke

☐

If you 'still smoke' how many years have you smoked?

/ Years of smoking

7. Do you drink Alcohol?

Yes ☐

No ☐

If yes, how often do you drink alcohol? Please tick one

Most days

☐

3 to 4 days a week ☐

1 to 2 days per week

☐

1 to 2 days per month, or less

☐

SECTION 2: DURING HOSPITAL STAY

(Please mark your answer on the scale 0 – 10 from strongly disagree to strongly agree)

1.

During my hospital stay I was anxious about my family at home:

Yes

No

0

1

2

3

4

5

6

7

8

9

10

Strongly Disagree

Strongly Agree

2.

Do you have any pets at home (dog, cat, etc)?

Yes

No

0

1

2

3

4

5

6

7

8

9

10

Strongly Disagree

Strongly Agree

During my hospital stay, I was anxious about my pets:

Yes

No

0

1

2

3

4

5

6

7

8

9

10

Strongly Disagree

Strongly Agree

Please State:

3.

During my hospital stay I was anxious about the security of my home:

Yes

No

0

1

2

3

4

5

6

7

8

9

10

Strongly Disagree

Strongly Agree

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4. Whilst in Hospital, after your operation, have you experienced any of the following:

<p>Pain: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, please rate the degree of pain:</p> <p>0 1 2 3 4 5 6 7 8 9 10</p> <p>None Severe</p> <p>Please rate how this was dealt with:</p> <p>0 1 2 3 4 5 6 7 8 9 10</p> <p>Poor Excellent</p>	<p>Constipation: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, please rate the constipation:</p> <p>0 1 2 3 4 5 6 7 8 9 10</p> <p>None Severe</p> <p>Please rate how this was dealt with:</p> <p>0 1 2 3 4 5 6 7 8 9 10</p> <p>Poor Excellent</p>
<p>Disturbed sleep: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, please rate the degree of sleep problem:</p> <p>0 1 2 3 4 5 6 7 8 9 10</p> <p>None Severe</p> <p>Please rate how this was dealt with:</p> <p>0 1 2 3 4 5 6 7 8 9 10</p> <p>Poor Excellent</p>	<p>Mobility: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, please rate the degree of difficulty:</p> <p>0 1 2 3 4 5 6 7 8 9 10</p> <p>None Severe</p> <p>Please rate how this was dealt with:</p> <p>0 1 2 3 4 5 6 7 8 9 10</p> <p>Poor Excellent</p>
<p>Wound infection: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, please rate the degree of infection:</p> <p>0 1 2 3 4 5 6 7 8 9 10</p> <p>None Severe</p> <p>Please rate how this was dealt with:</p> <p>0 1 2 3 4 5 6 7 8 9 10</p> <p>Poor Excellent</p>	<p>Anxiety: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/></p> <p>If yes, please rate the degree of anxiety:</p> <p>0 1 2 3 4 5 6 7 8 9 10</p> <p>None Severe</p> <p>Please rate how this was dealt with:</p> <p>0 1 2 3 4 5 6 7 8 9 10</p> <p>Poor Excellent</p>

5. During your hospital stay did you receive information and advice on when to resume normal activities such as:

Housework	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Resume Sexual Activity	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Heavy Lifting	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Driving	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Return to Work	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Exercise	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>

If yes, was this information given to you by: *(you may tick more than one box)*

Hospital Doctor	<input type="checkbox"/>	Specialist Nurse	<input type="checkbox"/>	Ward Nurse	<input type="checkbox"/>	Other	<input type="checkbox"/>
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6. During your hospital stay did you receive information and advice on any of the following lifestyle issues such as:

Self Breast Examination	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	HRT	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Osteoporosis	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Smoking	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Alcohol	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Healthy Diet	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>

If yes, was this information given to you by: *(you may tick more than one box)*

Hospital Doctor	<input type="checkbox"/>	Specialist Nurse	<input type="checkbox"/>	Ward Nurse	<input type="checkbox"/>	Other	<input type="checkbox"/>
-----------------	--------------------------	------------------	--------------------------	------------	--------------------------	-------	--------------------------

If no, would you have liked to receive information and advice on lifestyle issues?

Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
-----	--------------------------	----	--------------------------

7. Do you think you would follow any of the information and advice on the following lifestyle issues?

Self Breast Examination	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	HRT	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Osteoporosis	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Smoking	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
Alcohol	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>	Healthy Diet	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>

8. Please rate the amount and quality of information given to you by the following people:

Doctor

0

1

2

3

4

5

6

7

8

9

10

None

Excellent

Specialist Nurse

0

1

2

3

4

5

6

7

8

9

10

None

Excellent

Ward Nurse

0

1

2

3

4

5

6

7

8

9

10

None

Excellent

9. How satisfied were you with your care experience in hospital?

Excellent ☐

Very Good ☐

Good ☐

Fair ☐

Poor ☐

10. Do you have any suggestions or comments that you think may improve the service?

Yes ☐

No ☐

If yes, please state:

SECTION 3: DISCHARGE FROM HOSPITAL

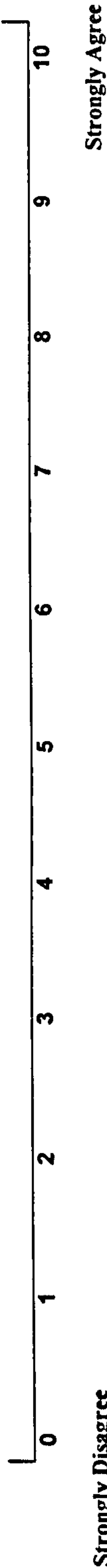
1.	When you were discharged home did you know how to contact the hospital?	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
	If yes, was it helpful to have a means of contacting staff when you got home?	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
If yes, please comment					
2.	Did you feel you got home:	Too soon	<input type="checkbox"/>	At the right time	<input type="checkbox"/>
				Not soon enough	<input type="checkbox"/>
3.	Were you given any discharge medication?	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
4.	Was instruction on discharge medication given to you?	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
	If yes, who gave you instruction (you may tick more than one box)				
	Doctor	<input type="checkbox"/>	Gynaecology Specialist Nurse	<input type="checkbox"/>	Ward Nurse
				Other	<input type="checkbox"/>
5.	Was HRT started during this admission?	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>

6. When at home, after your operation did you experience any problems with the following:

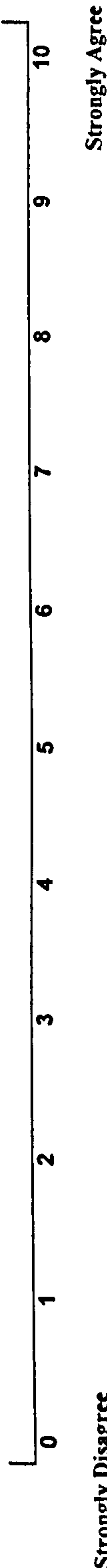
Pain: If yes, please rate the degree of pain: 0 1 2 3 4 5 6 7 8 9 10 None Severe Please rate how this was dealt with: 0 1 2 3 4 5 6 7 8 9 10 Poor Excellent	Constipation: If yes, please rate the constipation: 0 1 2 3 4 5 6 7 8 9 10 None Severe Please rate how this was dealt with: 0 1 2 3 4 5 6 7 8 9 10 Poor Excellent
Disturbed sleep: If yes, please rate the degree of sleep problem: 0 1 2 3 4 5 6 7 8 9 10 None Severe Please rate how this was dealt with: 0 1 2 3 4 5 6 7 8 9 10 Poor Excellent	Mobility: If yes, please rate the degree of difficulty: 0 1 2 3 4 5 6 7 8 9 10 None Severe Please rate how this was dealt with: 0 1 2 3 4 5 6 7 8 9 10 Poor Excellent
Wound infection: If yes, please rate the degree of infection: 0 1 2 3 4 5 6 7 8 9 10 None Severe Please rate how this was dealt with: 0 1 2 3 4 5 6 7 8 9 10 Poor Excellent	Anxiety: If yes, please rate the degree of anxiety: 0 1 2 3 4 5 6 7 8 9 10 None Severe Please rate how this was dealt with: 0 1 2 3 4 5 6 7 8 9 10 Poor Excellent

(Please mark your answer on the scale 0 – 10 from strongly disagree to strongly agree)

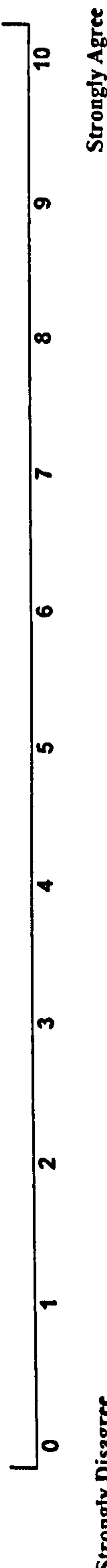
7. I was well prepared for discharge home?



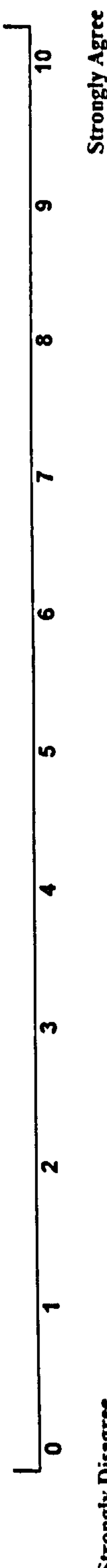
8. I felt confident I could contact the Specialist Nurse at anytime:



9. I felt confident I could contact the Ward Nurse at anytime:



10. It was more peaceful and quiet at home than in hospital:



11. Following discharge, were you visited at home by a Specialist Gynaecology Nurse? Yes ☐ No ☐

If yes, did you find the Specialist Nurse visit worthwhile? Yes ☐ No ☐

Please comment

SECTION 4: MILESTONES OF RECOVERY

1.

Did you receive enough information about your expected recovery and return to normal?

Yes☐No☐

Please give comments

2.

Were you told when you could return to work?

Yes☐No☐

If yes, what were you told:

Days

/

Weeks

3.

How long was it before you got back to normal? Please state

Days

/

Weeks

4.

How much time were you off from work? Please state

Days

/

Weeks

5.

Were you given any information and advice on the following lifestyle issues?

HRT

Smoking

Healthy Diet

Yes☐

Yes☐

Yes☐

No☐

No☐

No☐

Self Breast Examination

Alcohol

Exercise

Yes☐

Yes☐

Yes☐

No☐

No☐

No☐

If yes, did you follow any of the information and advice on lifestyle issues such as:

HRT

Smoking

Healthy Diet

Yes☐

Yes☐

Yes☐

No☐

No☐

No☐

Self Breast Examination

Alcohol

Exercise

Yes☐

Yes☐

Yes☐

No☐

No☐

No☐

246

6. Please rate the amount and quality of information given to you by the following people:

Doctor	<div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div></div>										
	0	1	2	3	4	5	6	7	8	9	10
	None					Excellent					

Specialist Nurse	<div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div></div>										
	0	1	2	3	4	5	6	7	8	9	10
	None					Excellent					

Ward Nurse	<div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div></div>										
	0	1	2	3	4	5	6	7	8	9	10
	None					Excellent					

7. Do you carry out breast examination? Yes ☐ No ☐

If yes, is this because:
You have always done this ☐ Advised by Specialist Nurse ☐ Advised by Ward Nurse ☐

Other ☐ Please state:

13. Have you received treatment from your General Practitioner

If so please state:

14. Since discharge home, have you had contact with any of the services listed below?

	Yes	No	Number of visits
Dietician	<input type="checkbox"/>	<input type="checkbox"/>	_____
Physiotherapist	<input type="checkbox"/>	<input type="checkbox"/>	_____
Social Worker	<input type="checkbox"/>	<input type="checkbox"/>	_____
Occupational Therapist	<input type="checkbox"/>	<input type="checkbox"/>	_____

If yes, please give reason in your own words:

--	--	--	--	--	--	--	--	--	--

GYNAECOLGY NURSING QUESTIONNAIRE

This questionnaire asks about your experience in Ward G9 at the Western Infirmary

The information you provide will be treated in the strictest confidence.

For the following questions, unless otherwise instructed, please tick the most appropriate response.

SECTION 1: BACKGROUND DETAIL ON YOURSELF

1.

How would you rate your general health, compared with other women your age?

Worse than most

About the same as others

Better than most

☐

☐

☐
2.

Do you work? *Please tick*

Yes, Full Time

Yes, Part Time

No

Retired

☐

☐

☐

☐
- What is your job, or what was your job when you last worked?

3.

How many babies have you had altogether?

What was the year of your last pregnancy?

How many of these children do you still have living at home with you?

Do you have other children living with you (*adopted etc*)?

Please write in number 0 if none

/

/

/

/

4.

Do you take regular exercise?

Yes

No

☐

☐

If yes, please describe:

5.

Do you carry out self examination of breasts?

Yes

No

☐

☐

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4. Whilst in Hospital, after your operation, have you experienced any of the following:

Pain: Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please rate the degree of pain: 0 1 2 3 4 5 6 7 8 9 10 None Severe Please rate how this was dealt with: 0 1 2 3 4 5 6 7 8 9 10 Poor Excellent	Constipation: Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please rate the constipation: 0 1 2 3 4 5 6 7 8 9 10 None Severe Please rate how this was dealt with: 0 1 2 3 4 5 6 7 8 9 10 Poor Excellent
Disturbed sleep: Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please rate the degree of sleep problem: 0 1 2 3 4 5 6 7 8 9 10 None Severe Please rate how this was dealt with: 0 1 2 3 4 5 6 7 8 9 10 Poor Excellent	Mobility: Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please rate the degree of difficulty: 0 1 2 3 4 5 6 7 8 9 10 None Severe Please rate how this was dealt with: 0 1 2 3 4 5 6 7 8 9 10 Poor Excellent
Wind: Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please rate the degree of wind 0 1 2 3 4 5 6 7 8 9 10 None Severe Please rate how this was dealt with: 0 1 2 3 4 5 6 7 8 9 10 Poor Excellent	Anxiety: Yes <input type="checkbox"/> No <input type="checkbox"/> If yes, please rate the degree of anxiety: 0 1 2 3 4 5 6 7 8 9 10 None Severe Please rate how this was dealt with: 0 1 2 3 4 5 6 7 8 9 10 Poor Excellent

5.

During your hospital stay did you receive information and advice on when to resume normal activities such as:

Housework

Heavy Lifting

Return to Work

Yes

Yes

Yes

No

No

No

Resume Sexual Activity

Driving

Exercise

Yes

Yes

Yes

No

No

No

If yes, was this information given to you by: *(you may tick more than one box)*

Hospital Doctor

Specialist Nurse

Ward Nurse

Other

☐

☐

☐

☐

6.

During your hospital stay did you receive information and advice on any of the following lifestyle issues such as:

Self Breast Examination

Osteoporosis

Alcohol

Yes

Yes

Yes

No

No

No

HRT

Smoking

Healthy Diet

Yes

Yes

Yes

No

No

No

If yes, was this information given to you by: *(you may tick more than one box)*

Hospital Doctor

Specialist Nurse

Ward Nurse

Other

☐

☐

☐

☐

7.

Do you think you would follow any of the information and advice on the following lifestyle issues?

Self Breast Examination

Osteoporosis

Alcohol

Yes

Yes

Yes

No

No

No

HRT

Smoking

Healthy Diet

Yes

Yes

Yes

No

No

No

8. Please rate the amount and quality of information given to you by the following people:

Doctor

0	1	2	3	4	5	6	7	8	9	10
										Excellent

None

Specialist Nurse

0	1	2	3	4	5	6	7	8	9	10
										Excellent

None

Ward Nurse

0	1	2	3	4	5	6	7	8	9	10
										Excellent

None

9. How satisfied were you with your care experience in hospital?

Excellent	<input type="checkbox"/>	Very Good	<input type="checkbox"/>	Good	<input type="checkbox"/>	Fair	<input type="checkbox"/>	Poor	<input type="checkbox"/>
-----------	--------------------------	-----------	--------------------------	------	--------------------------	------	--------------------------	------	--------------------------

10. Do you have any suggestions or comments that you think may improve the service?

Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
-----	--------------------------	----	--------------------------

If yes, please state:

--	--	--	--	--	--	--	--	--	--

GYNAECLOGY NURSING QUESTIONNAIRE

This questionnaire asks about your experience at home following discharge from hospital
in Ward G9 at the Western Infirmary

The information you provide will be treated in the strictest confidence.

For the following questions, unless otherwise instructed please tick the most appropriate response.

SECTION 3: DISCHARGE FROM HOSPITAL

1.	When you were discharged home did you know how to contact the hospital?	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
	If yes, was it helpful to have a means of contacting staff when you got home?	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
If yes, please comment:					
2.	Did you feel you got home:	Too soon	<input type="checkbox"/>	At the right time	<input type="checkbox"/>
				Not soon enough	<input type="checkbox"/>
3.	Were you given any discharge medication?	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
4.	Was instruction on discharge medication given to you?	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>
	If yes, who gave you instruction (<i>you may tick more than one box</i>)				
	Doctor	<input type="checkbox"/>	Gynaecology Specialist Nurse	<input type="checkbox"/>	Ward Nurse
				Other	<input type="checkbox"/>
5.	Was HRT started during this admission?	Yes	<input type="checkbox"/>	No	<input type="checkbox"/>

(Please mark your answer on the scale 0 – 10 from strongly disagree to strongly agree)

7. I was well prepared for discharge home?

	0	1	2	3	4	5	6	7	8	9	10	
Strongly Disagree											Strongly Agree	

8. I felt confident I could contact the Specialist Nurse at anytime:

	0	1	2	3	4	5	6	7	8	9	10	
Strongly Disagree											Strongly Agree	

9. I felt confident I could contact the Ward Nurse at anytime:

	0	1	2	3	4	5	6	7	8	9	10	
Strongly Disagree											Strongly Agree	

10. It was more peaceful and quiet at home than in hospital:

	0	1	2	3	4	5	6	7	8	9	10	
Strongly Disagree											Strongly Agree	

11. Following discharge, were you visited at home by a Specialist Gynaecology Nurse?

Yes ☐ No ☐

If yes, did you find the Specialist Nurse visit worthwhile?

Yes ☐ No ☐

Please comment:

SECTION 4: MILESTONES OF RECOVERY

1.

Did you receive enough information about your expected recovery and return to normal?

Yes☐No☐

Please give comments

2.

Were you told when you could return to work?

Yes☐No☐

If yes, what were you told:

3.

How long was it before you got back to normal? Please state

Days

/

Weeks

4.

How much time were you off from work? Please state

Days

/

Weeks

5.

Were you given any information and advice on the following lifestyle issues?

HRT

Yes☐No☐

Self Breast Examination

Yes☐No☐

Smoking

Yes☐No☐

Alcohol

Yes☐No☐

Healthy Diet

Yes☐No☐

Exercise

Yes☐No☐

If yes, did you follow any of the information and advice on lifestyle issues such as:

HRT

Yes☐No☐

Self Breast Examination

Yes☐No☐

Smoking

Yes☐No☐

Alcohol

Yes☐No☐

Healthy Diet

Yes☐No☐

Exercise

Yes☐No☐

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6. Please rate the amount and quality of information given to you by the following people:

Doctor											
	0	1	2	3	4	5	6	7	8	9	10
None											Excellent

Specialist Nurse											
	0	1	2	3	4	5	6	7	8	9	10
None											Excellent

Ward Nurse											
	0	1	2	3	4	5	6	7	8	9	10
None											Excellent

7. Do you carry out self breast examination?

Yes ☐ No ☐

If yes, is this because:

You have always done this	<input type="checkbox"/>	Advised by Specialist Nurse	<input type="checkbox"/>	Advised by Ward Nurse	<input type="checkbox"/>
---------------------------	--------------------------	-----------------------------	--------------------------	-----------------------	--------------------------

Other	<input type="checkbox"/>	Please state:
-------	--------------------------	---------------------

8. Do you carry out regular exercise? Yes ☐ No ☐
- If yes, is this because:
- You have always done this ☐ Advised by Specialist Nurse ☐ Advised by Ward Nurse ☐
- Other ☐ Please state:
9. How satisfied were you with your overall care experience?
- Excellent ☐ Very Good ☐ Good ☐ Fair ☐ Poor ☐
10. Have you seen your General Practitioner since you left hospital? Yes ☐ No ☐
11. If yes, how many times in the past 6 weeks – 3 months? *Please state* ____/____
- Where did you see a G.P?
- Health Centre/Surgery ☐ At home ☐ Out of hours service ☐
12. What was your main reason for seeing your G.P?
- Directly related to Gynaecological Surgery ☐ Routine Visit ☐
- Other reason, please state:

13. Have you received treatment from your GP for:

Wound infection ☐ Constipation ☐ Urine Infection ☐

Other reason, please state:

14. Since discharge home, have you had contact with any of the services listed below?

	Yes	No	Number of visits
Dietician	<input type="checkbox"/>	<input type="checkbox"/>	_____
Physiotherapist	<input type="checkbox"/>	<input type="checkbox"/>	_____
Social Worker	<input type="checkbox"/>	<input type="checkbox"/>	_____
Occupational Therapist	<input type="checkbox"/>	<input type="checkbox"/>	_____

If yes, please give reason in your own words:

Calculation of SF-36 Health Domain Scores

1. Physical function (PF)

$$PF = 3a + 3b + 3c + 3d + 3e + 3f + 3h + 3I + 3j$$

$$\text{Physical function score} = (PF - 10)/20 * 100$$

2. Role limitation due to physical problems (RP)

$$RP = 4a + 4b + 4c + 4d$$

$$\text{Role limitation due to physical problems score} = (RP/4) * 100$$

3. Role limitation due to emotional problems (RE)

$$RE = 5a + 5b + 5c$$

$$\text{Role limitations due to emotional problems score} = (RE/3) * 100$$

4. Social Functioning (SF)

$$SF = 6 + 9j$$

$$\text{Social functioning score} = ((SF-2)/9) * 100$$

5. Mental health (MH)

$$MH = 9b + 9c + 9d + 9f + 9h$$

$$\text{Mental health score} = ((MH-5)/25) * 100$$

6. Energy/vitality (EV)

$$EV = 9a + 9e + 9g + 9i$$

$$\text{Energy/vitality score} = ((EV-4)/20) * 100$$

7. Pain (P)

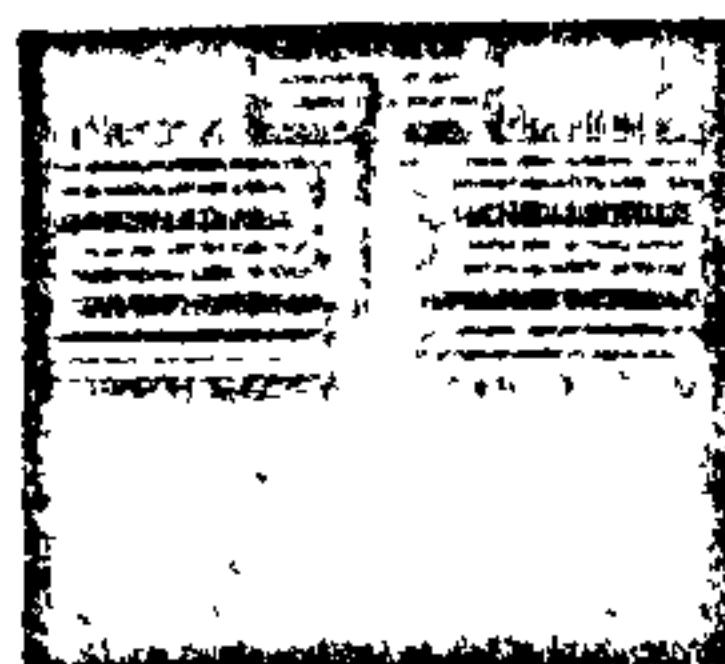
$$P = 7 + 8$$

$$\text{Pain} = ((P-2)/9) * 100$$

8. General Health Perception (GHP)

$$GHP = 1 + 10a + 10b + 10c + 10d$$

$$\text{General health perceptions} = ((GHP-5)/20) * 100$$



West Glasgow Hospitals

Surgical Specialties & Nephrology Directorate

Western Infirmary

Dumbarton Road

Glasgow G11 6NT

Tel: 0141 211 2339

Fax: 0141 211 1910

Our Ref: HD/rm/hdmves.study.doc

28 September 1999

Dear

RE: GYNAECOLOGY NURSING STUDY

Thank you for taking part in the Gynaecology Nursing Study. Part of the study requires that two follow-up questionnaires be completed.

I would be very grateful if you could complete both questionnaires and return them to me in the stamped addressed envelope provided as soon as possible.

This should only take about 10 minutes of your time as the questionnaires are similar to those completed during your hospital stay.

If you have any questions I can be contacted at the Western Infirmary on 0141 211 2339.

Thank you for your co-operation.

I look forward to hearing from you.

Kind regards.

Yours sincerely

Ann Gordon
Research Nurse

Enc.

Incorporating the Western Infirmary, Gartnavel General Hospital,
The Glasgow Homoeopathic Hospital, Drumchapel Hospital and Blawarthill Hospital



Accredited by the
King's Fund Organisation Audit

RESOURCE DATA COLLECTION PROSPECTIVE CASE NOTE REVIEW

Patient details			
Name	Postcode:	Study number:	Group:
All diagnostic tests (circle for yes			
FBC	<input type="checkbox"/> YES <input type="checkbox"/> NO	G&S	<input type="checkbox"/> YES <input type="checkbox"/> NO
U&E's	<input type="checkbox"/> YES <input type="checkbox"/> NO	ECG	<input type="checkbox"/> YES <input type="checkbox"/> NO
X-ray	<input type="checkbox"/> YES <input type="checkbox"/> NO	Blood transfusion	<input type="checkbox"/> YES <input type="checkbox"/> NO
Other:			
Operation details			
Type of surgery.	Length of operation:		
Name of anaesthetist:	Name of surgeon:		
Immediate post-op analgesic			
Pre-medication	Please state:		
Morphine 1mg	<input type="checkbox"/> YES <input type="checkbox"/> NO	Zofran 4mg IM 6 hourly	<input type="checkbox"/> YES <input type="checkbox"/> NO
PCA 1mg/ml 5ml lock-out	<input type="checkbox"/> YES <input type="checkbox"/> NO	Calciparine 5,000 IU SC BD	<input type="checkbox"/> YES <input type="checkbox"/> NO
Cyclomorph 7.5 or 15mg IM	<input type="checkbox"/> YES <input type="checkbox"/> NO		
IV Fluids 4 hourly 2:1 Dextrose-saline 24/36 hours	<input type="checkbox"/> YES <input type="checkbox"/> NO		
IV antibiotics prophylactic dose	<input type="checkbox"/> YES <input type="checkbox"/> NO	Please state:	
Other (please state):			
Oral analgesic requirements			
Co-codomol 2 tabs 4-6 hourly	<input type="checkbox"/> YES <input type="checkbox"/> NO	Voltarol 50mg PR/Oral 8 hourly	<input type="checkbox"/> YES <input type="checkbox"/> NO
Discharge prescription 7 day supply			
Co-codomol 2 tabs 4-6 hourly	<input type="checkbox"/> YES <input type="checkbox"/> NO	Voltarol 50mg PR/Oral 8 hourly	<input type="checkbox"/> YES <input type="checkbox"/> NO
		Lactalose	<input type="checkbox"/> YES <input type="checkbox"/> NO
Other (antibiotics):			
Telephoned at home by Specialist Nurse <input type="checkbox"/> YES <input type="checkbox"/> NO (no of times):			
Visited at home by Specialist Nurse <input type="checkbox"/> YES <input type="checkbox"/> NO (no of times):			
Complications in hospital <input type="checkbox"/> YES <input type="checkbox"/> NO			
Additional surgery in hospital first op <input type="checkbox"/> YES <input type="checkbox"/> NO			
Please state additional surgery performed length of op (pain control, if same as previous, please state Yes/No): <input type="checkbox"/> YES <input type="checkbox"/> NO			
Other treatment in hospital first op Yes/No (Please state) Antibiotics <input type="checkbox"/> YES <input type="checkbox"/> NO			
Complications at home <input type="checkbox"/> YES <input type="checkbox"/> NO			
Re-admitted <input type="checkbox"/> YES <input type="checkbox"/> NO			
Additional surgery at readmission <input type="checkbox"/> YES <input type="checkbox"/> NO			
Other treatment in hospital re-admission Yes/No (Please state) Antibiotics <input type="checkbox"/> YES <input type="checkbox"/> NO			
Assessment of bladder function			
In-dwelling catheter at surgery	<input type="checkbox"/> YES <input type="checkbox"/> NO	UTI with positive culture	<input type="checkbox"/> YES <input type="checkbox"/> NO
Urinary retention post-op	<input type="checkbox"/> YES <input type="checkbox"/> NO	In/out catheter	<input type="checkbox"/> YES <input type="checkbox"/> NO
		Pyrexia	<input type="checkbox"/> YES <input type="checkbox"/> NO
Assessment of wound/perineum			
Mild	moderate	severe	erythema <input type="checkbox"/> YES <input type="checkbox"/> NO
		Wound dehissence	<input type="checkbox"/> YES <input type="checkbox"/> NO
		Positive wound swab	<input type="checkbox"/> YES <input type="checkbox"/> NO
		Return to theatre	<input type="checkbox"/> YES <input type="checkbox"/> NO
		Treatment	<input type="checkbox"/> YES <input type="checkbox"/> NO
		Antibiotics	<input type="checkbox"/> YES <input type="checkbox"/> NO
PV bleeding <input type="checkbox"/> YES <input type="checkbox"/> NO			
PV Bleeding Mild Moderate Severe			
PV Bleeding requiring treatment with antibiotics (vault haematoma) <input type="checkbox"/> YES <input type="checkbox"/> NO			
Haemorrhage requiring return to theatre <input type="checkbox"/> YES <input type="checkbox"/> NO			
Please state surgery length of op (pain control, if same as previous, please state Yes/No): <input type="checkbox"/> YES <input type="checkbox"/> NO			
Readmission <input type="checkbox"/> YES <input type="checkbox"/> NO			
Reason			
Length of hospital stay			
Additional surgery <input type="checkbox"/> YES <input type="checkbox"/> NO			
Antibiotics <input type="checkbox"/> YES <input type="checkbox"/> NO			
Review clinic visit six weeks			
Condition since surgery			
Problems <input type="checkbox"/> YES <input type="checkbox"/> NO			
Discharge from clinic <input type="checkbox"/> YES <input type="checkbox"/> NO			
If problems please state:			

PUBLICATION

Publication: European Journal of Obstetrics & Gynaecology and Reproductive Biology. Dawes HA, Docherty T, Traynor I, Gilmore DH, Jardine AG, Knill-Jones R. Specialist nurse supported discharge in Gynaecology: a randomised comparison and economic evaluation.

Two posters presented at Scottish Executive Health Department Consensus Conference: New nursing roles - deciding the future for Scotland 2004.

Poster 1:

Descriptive study of specialist nurses working in the west sector of Glasgow during 1998. Dawes H, Jardine AG, Knill-Jones R.

Poster 2:

A randomised comparison of specialist nurse supported discharge in Gynaecology. Dawes HA, Docherty T, Traynor I, Gilmore DH, Jardine AG, Knill-Jones R.

Full abstracts published in; Key Note Papers from Consensus Conference; 2003 Nov 17-18; Edinburgh, UK. Edinburgh; Scottish Executive; 2004.

